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Pulitzer et al.

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(54) **SYSTEM AND METHOD FOR VARIABLE FUNCTION MOBILE APPLICATION FOR PROVIDING MEDICAL TEST RESULTS USING VISUAL INDICIA TO DETERMINE MEDICAL TEST FUNCTION TYPE**

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(72) Inventors: **Jovan Hutton Pulitzer**, Frisco, TX (US); **Henry Joseph Legere, III**, Austin, TX (US)

(73) Assignee: **RELIANT IMMUNE DIAGNOSTICS, INC.**, Austin, TX (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(22) Filed: **Nov. 6, 2017**

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Related U.S. Application Data

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(Continued)

(51) **Int. Cl.**
G01N 33/558 (2006.01)
G01N 33/53 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***G01N 33/558*** (2013.01); ***G01N 33/5302*** (2013.01); ***G01N 33/543*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC G01N 2035/00108; G01N 2035/00118; G01N 33/558; G01N 2035/00128;
(Continued)

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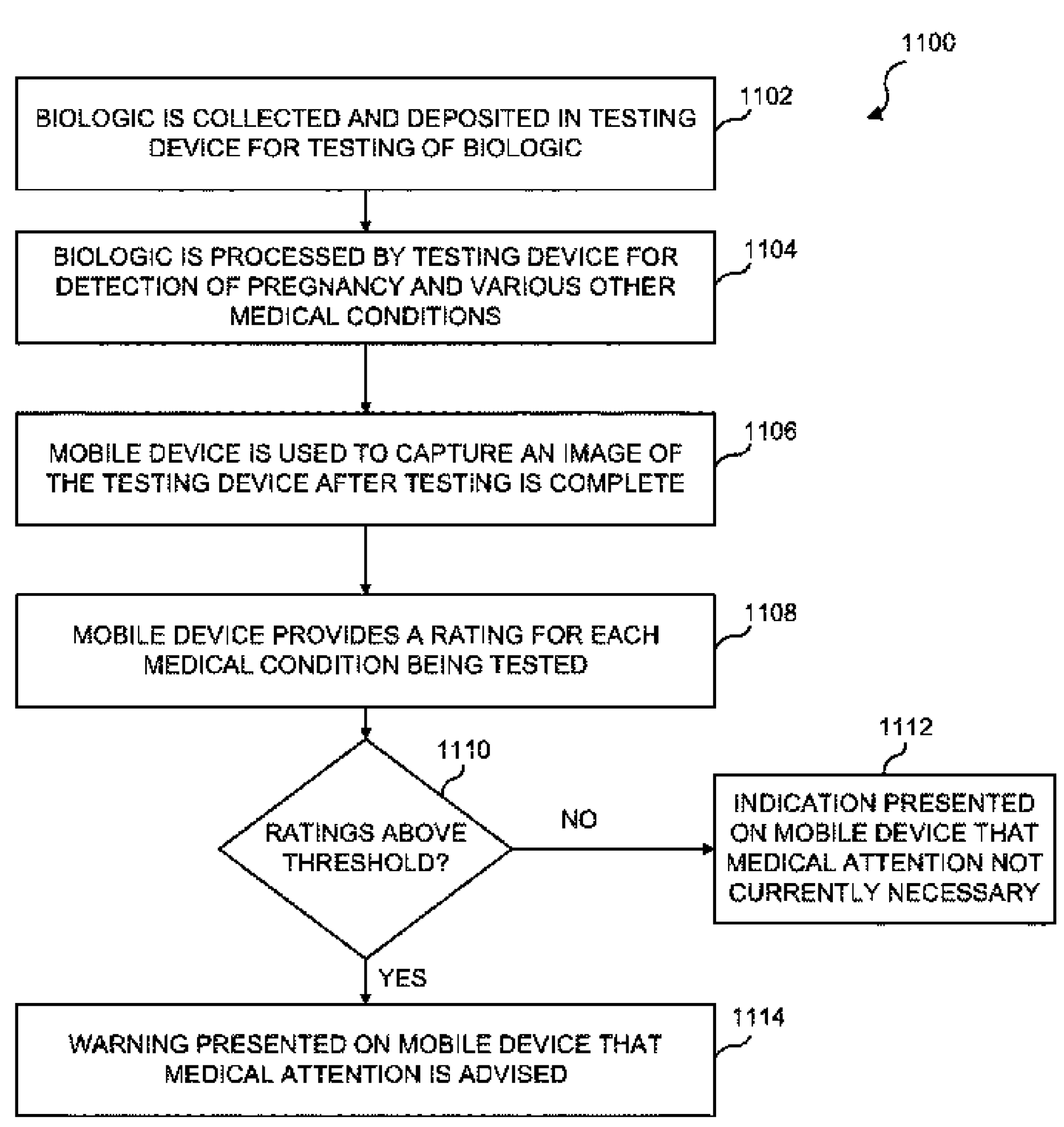
(Continued)

Primary Examiner — Rebecca M Giere
Assistant Examiner — Xiaoyan Zou

(57) **ABSTRACT**

A method for image analysis of medical test results, comprising receiving information from a mobile device application regarding a test performed using a testing device, wherein the testing device includes a plurality of immunoassay test strips and at least one test function indicator on a surface thereof, wherein the mobile device application is configured to recognize the at least one test function indicator to trigger performance of one or more of the plurality of medical test functions, receiving at the server an image of the testing device from the mobile device application, determining by the server RGB values for a plurality of pixels of the image, normalizing by the server the RGB values into a single value, comparing the single value to a control value,
(Continued)



and providing by the server a risk indicator, wherein the risk indicator indicates a likelihood of a presence of a medical condition.

15 Claims, 19 Drawing Sheets

Related U.S. Application Data

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G06T 7/00 (2017.01)
G01N 33/543 (2006.01)
G06T 7/90 (2017.01)
G01N 33/569 (2006.01)

(52) **U.S. Cl.**
CPC ***G01N 33/56983*** (2013.01); ***G06T 7/0012*** (2013.01); ***G06T 7/90*** (2017.01); *G01N 2333/185* (2013.01); *G01N 2333/59* (2013.01); *G06T 2207/10024* (2013.01); *G06T 2207/30004* (2013.01)

(58) **Field of Classification Search**
CPC G01N 2021/7759; G01N 21/8483; G01N 2021/8488; G01N 2021/8494; G01N 33/54386; Y10S 435/97; B01L 2300/0825
USPC 436/514
See application file for complete search history.

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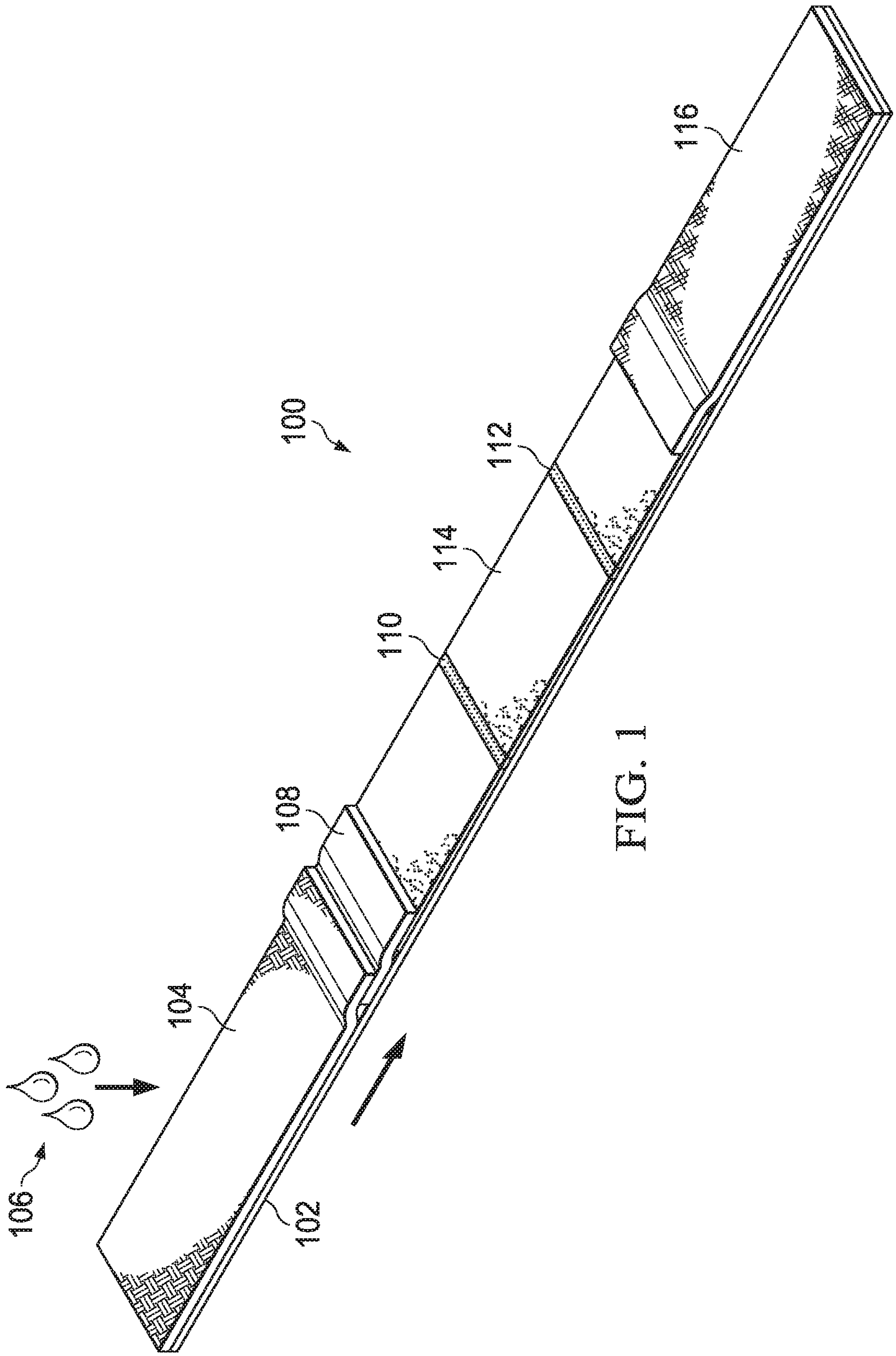

FIG. 1

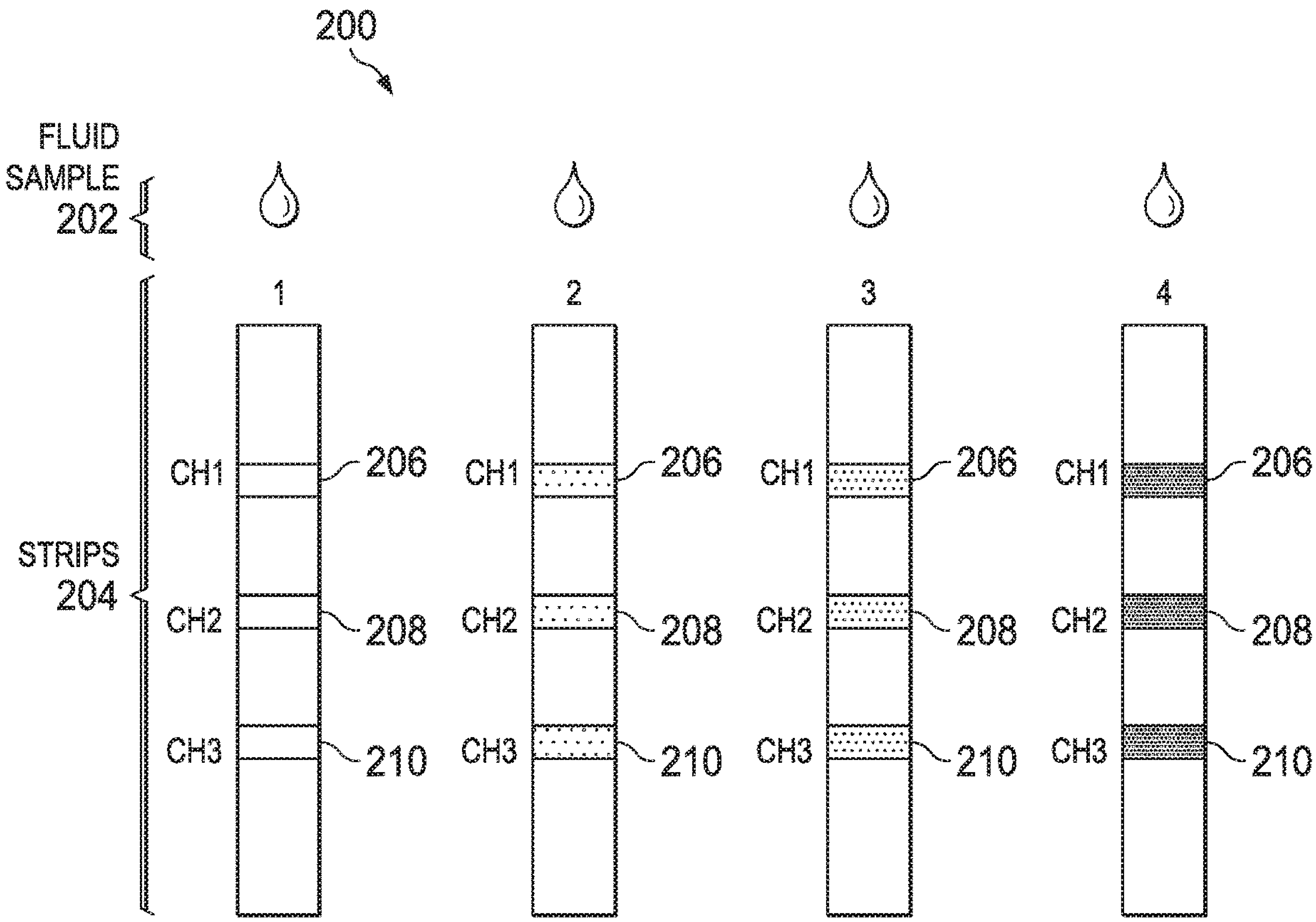

FIG. 2

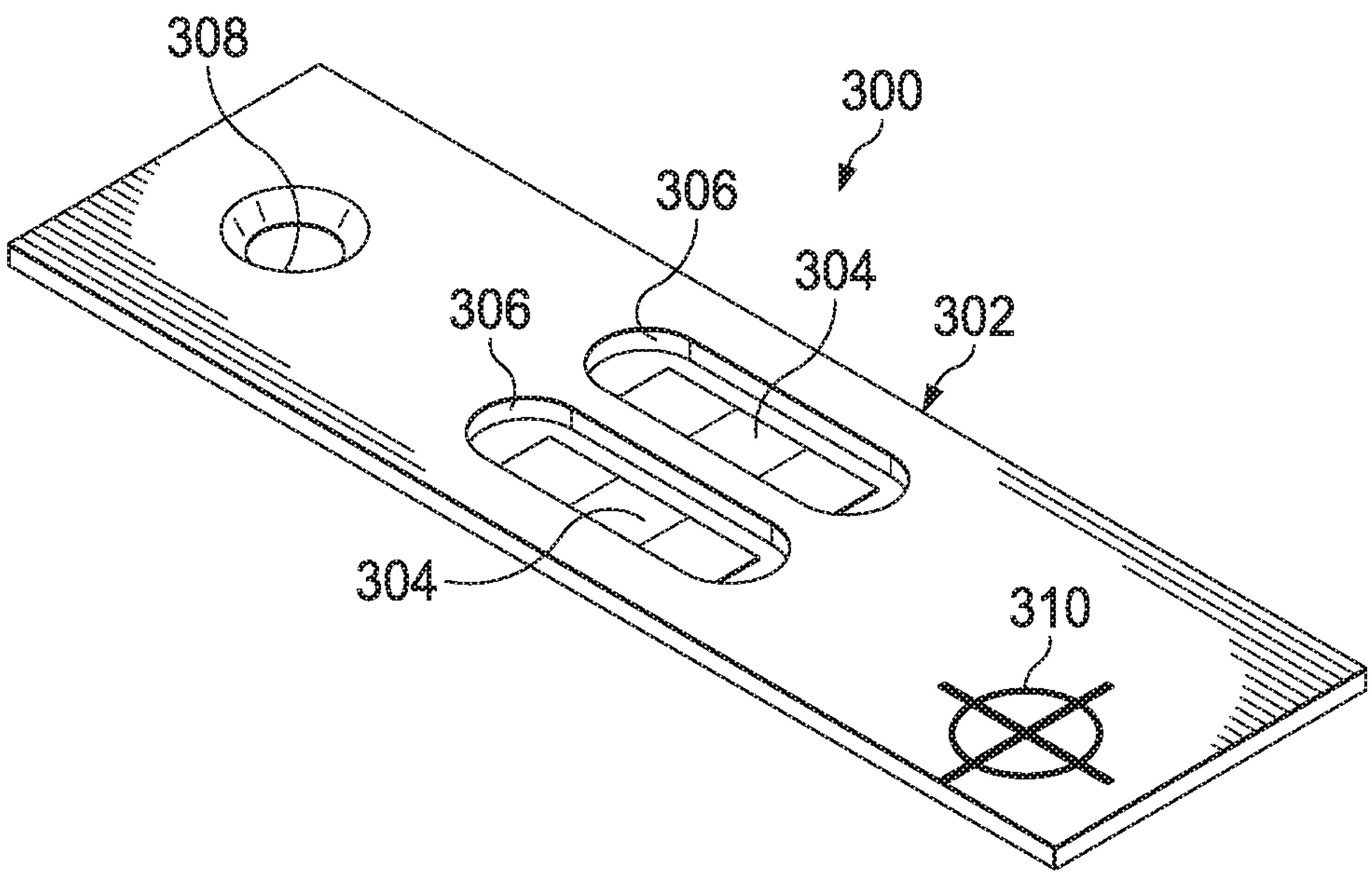

FIG. 3

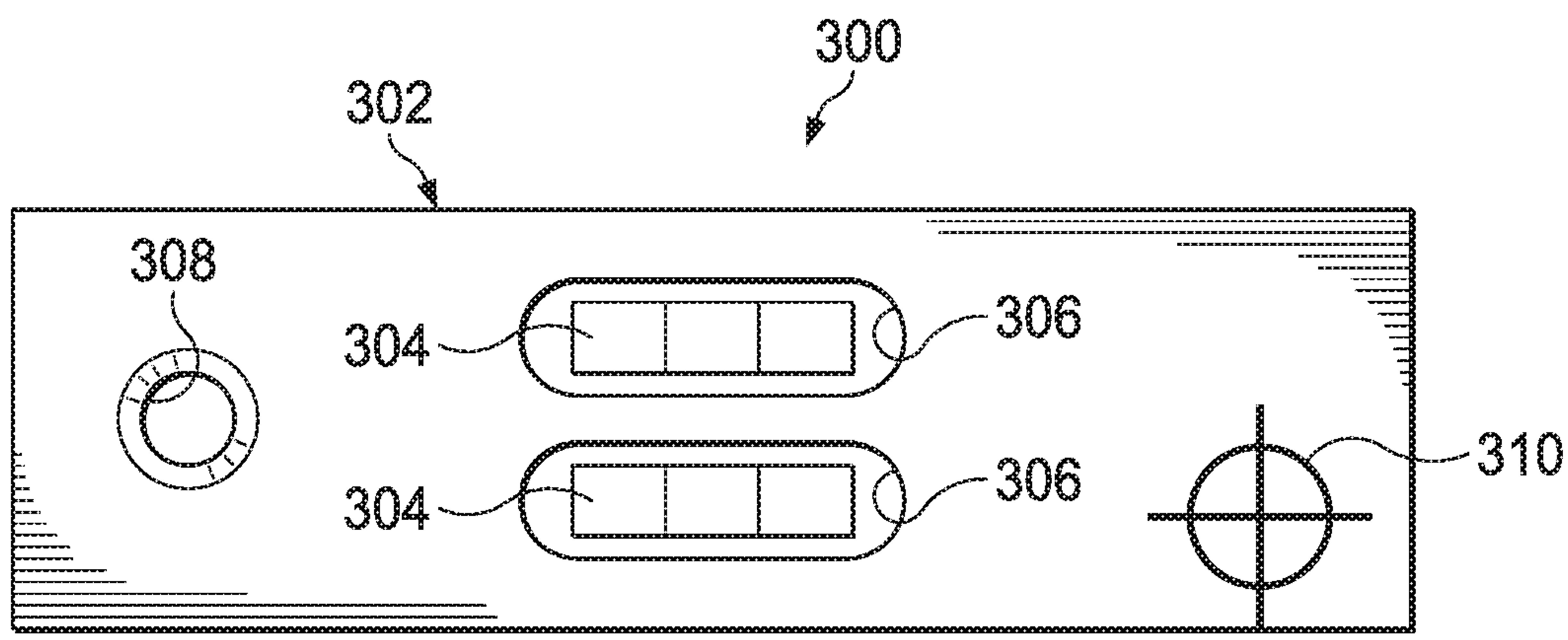

FIG. 4

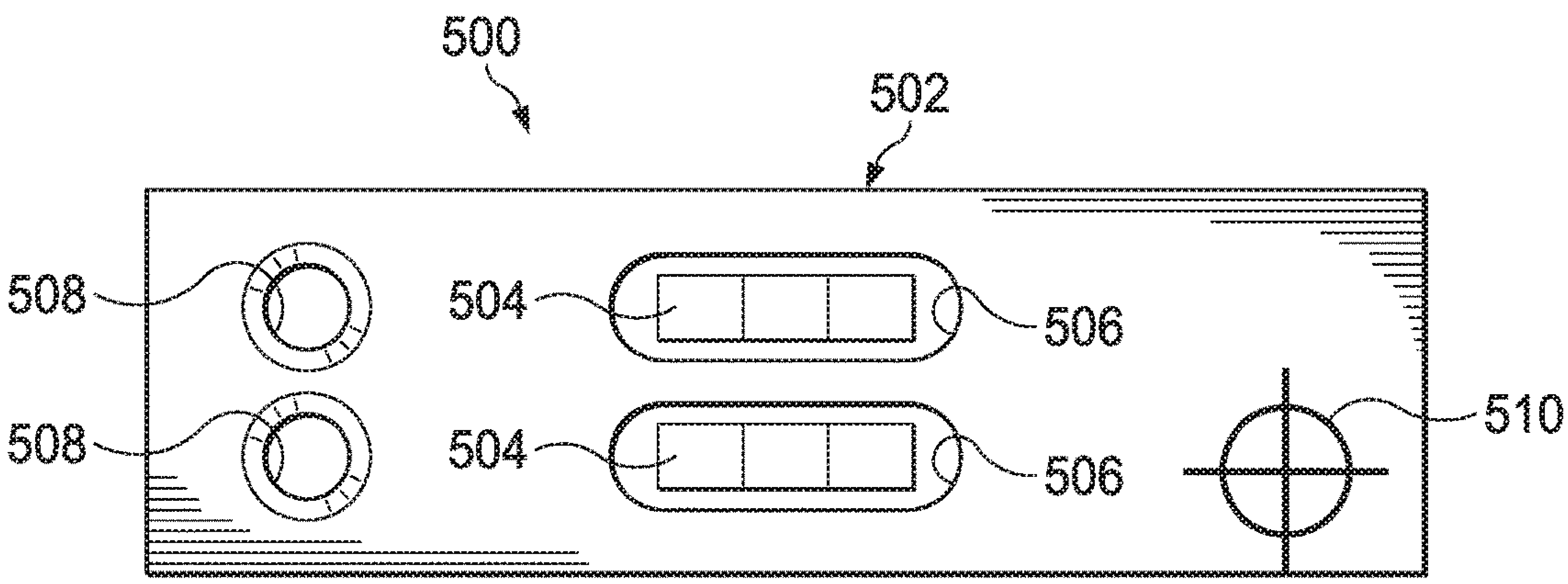
500
502
508
504
506
508
504
506
510

FIG. 5

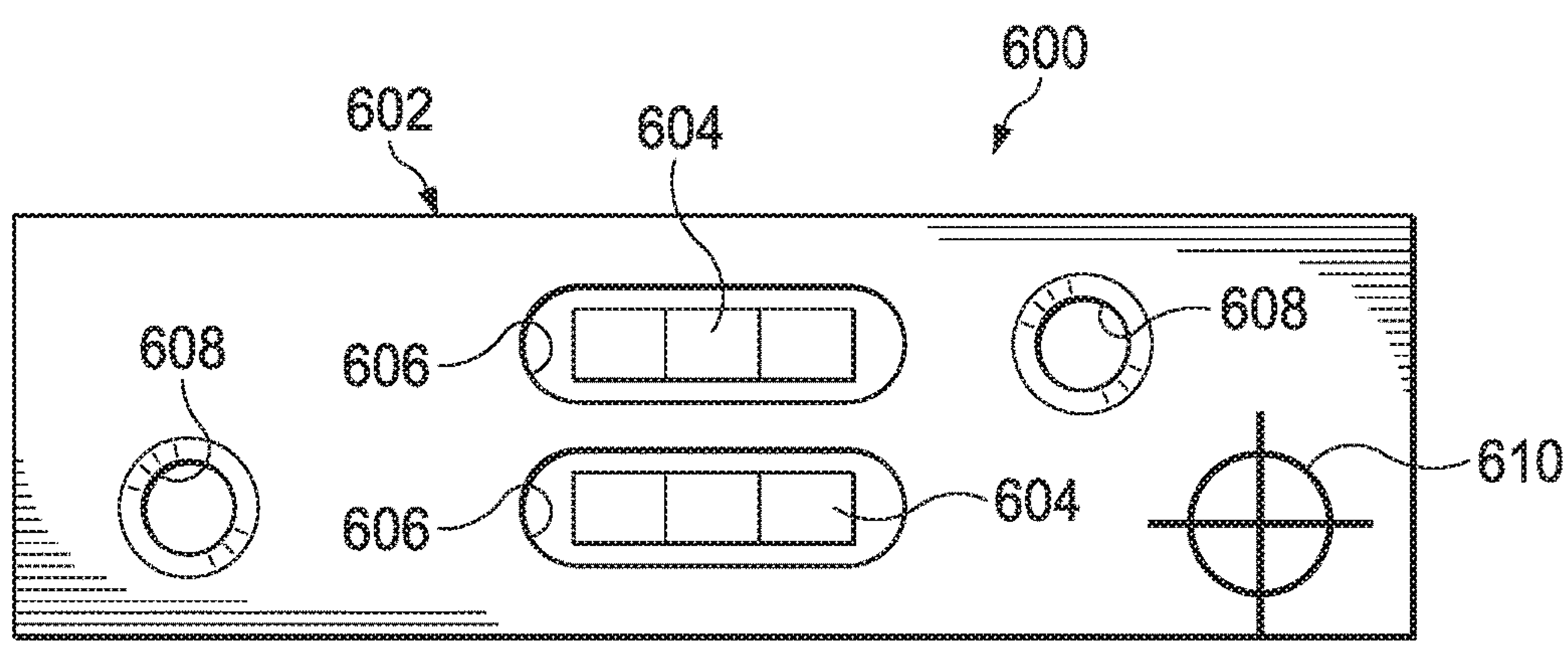
600
602
604
608
606
608
606
604
610

FIG. 6

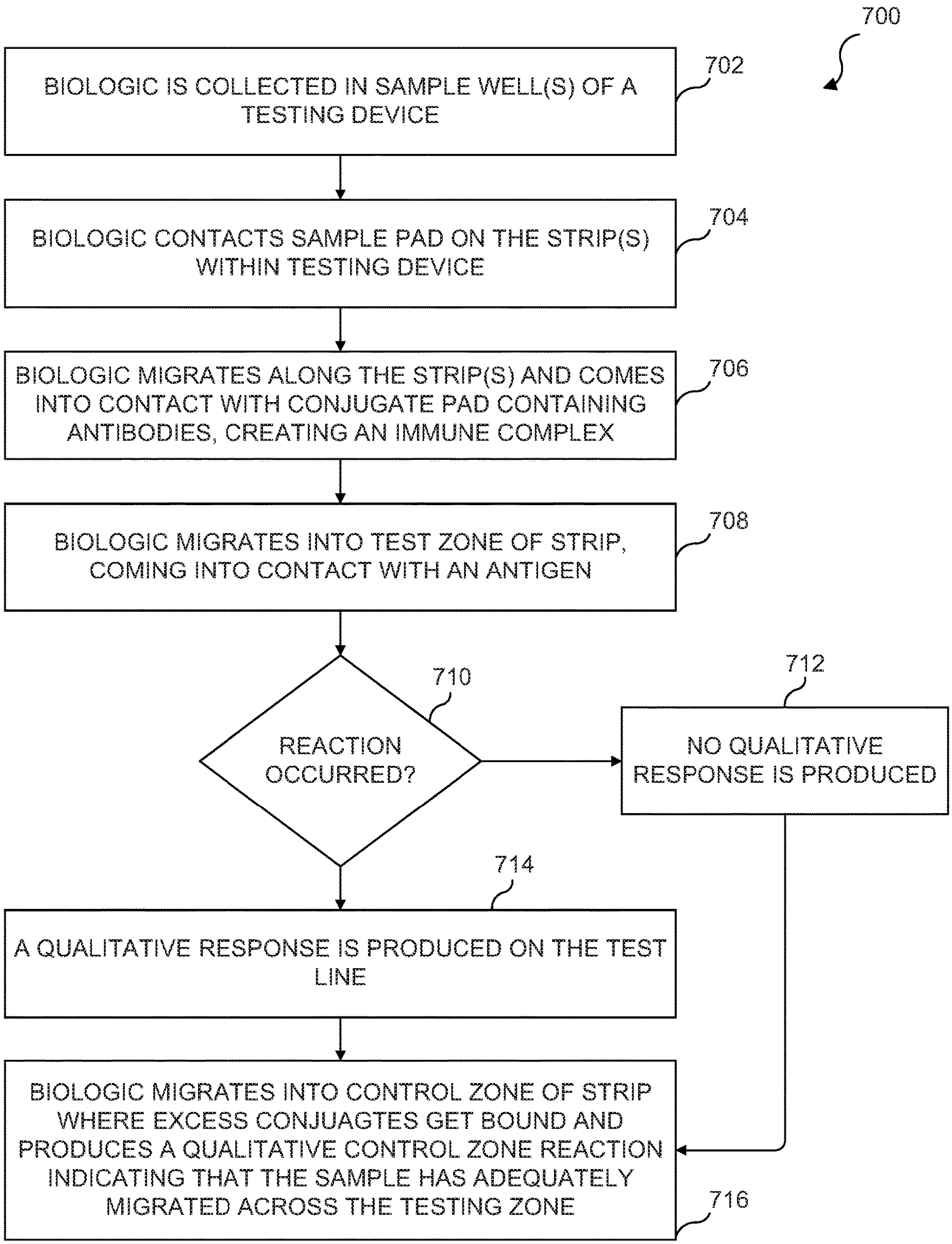
700
702
BIOLOGIC IS COLLECTED IN SAMPLE WELL(S) OF A TESTING DEVICE
704
BIOLOGIC CONTACTS SAMPLE PAD ON THE STRIP(S) WITHIN TESTING DEVICE
706
BIOLOGIC MIGRATES ALONG THE STRIP(S) AND COMES INTO CONTACT WITH CONJUGATE PAD CONTAINING ANTIBODIES, CREATING AN IMMUNE COMPLEX
708
BIOLOGIC MIGRATES INTO TEST ZONE OF STRIP, COMING INTO CONTACT WITH AN ANTIGEN
710
REACTION OCCURRED?
712
NO QUALITATIVE RESPONSE IS PRODUCED
714
A QUALITATIVE RESPONSE IS PRODUCED ON THE TEST LINE
BIOLOGIC MIGRATES INTO CONTROL ZONE OF STRIP WHERE EXCESS CONJUAGTES GET BOUND AND PRODUCES A QUALITATIVE CONTROL ZONE REACTION INDICATING THAT THE SAMPLE HAS ADEQUATELY MIGRATED ACROSS THE TESTING ZONE
716

FIG. 7

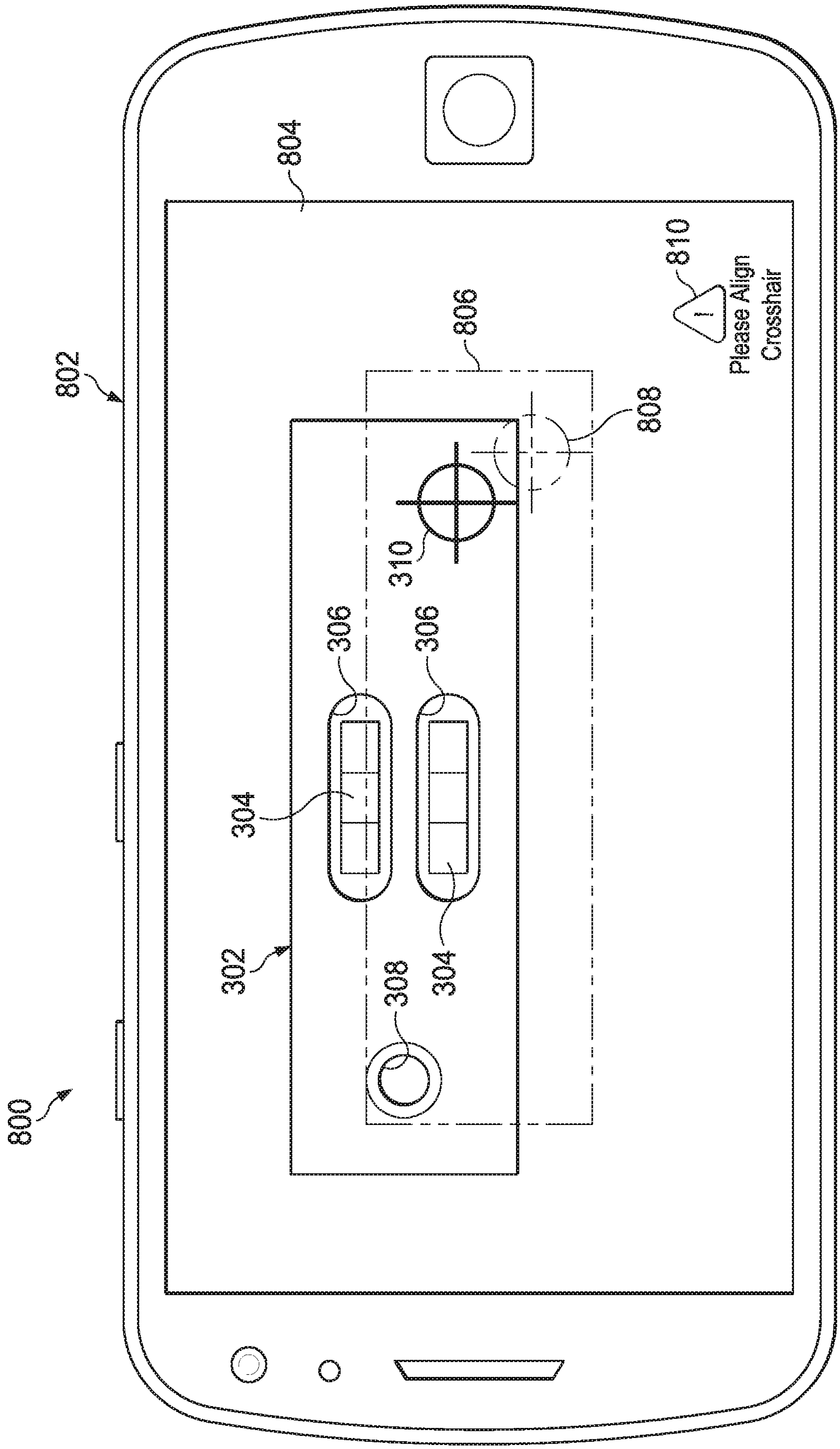
800
802
804
806
808
810
Please Align
Crosshair
302
304
304
306
306
308
310

FIG. 8A

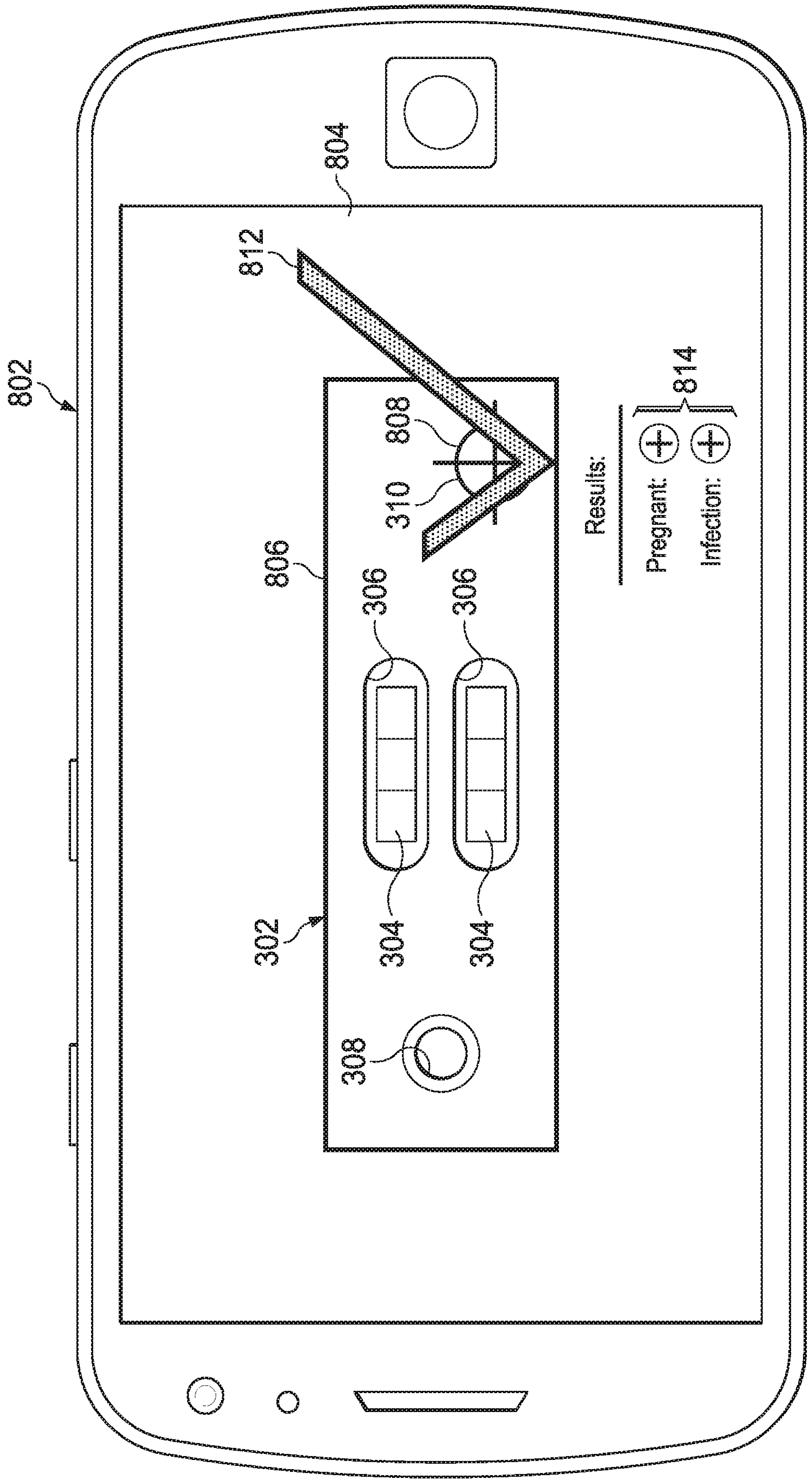
802
804
812
814
808
310
806
306
306
302
304
304
308
Results:
Pregnant:
Infection:

FIG. 8B

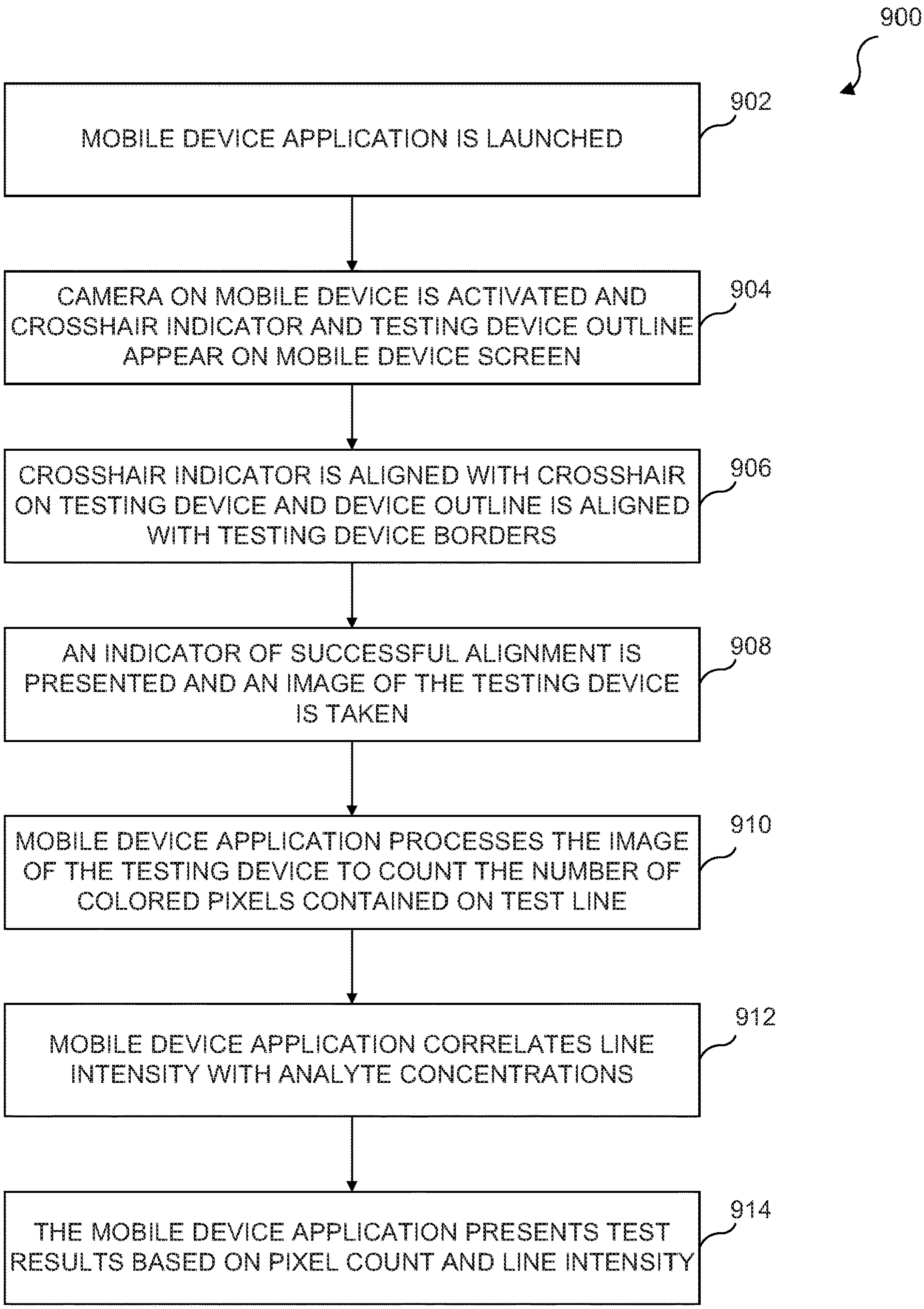
900
902
MOBILE DEVICE APPLICATION IS LAUNCHED
904
CAMERA ON MOBILE DEVICE IS ACTIVATED AND CROSSHAIR INDICATOR AND TESTING DEVICE OUTLINE APPEAR ON MOBILE DEVICE SCREEN
906
CROSSHAIR INDICATOR IS ALIGNED WITH CROSSHAIR ON TESTING DEVICE AND DEVICE OUTLINE IS ALIGNED WITH TESTING DEVICE BORDERS
908
AN INDICATOR OF SUCCESSFUL ALIGNMENT IS PRESENTED AND AN IMAGE OF THE TESTING DEVICE IS TAKEN
910
MOBILE DEVICE APPLICATION PROCESSES THE IMAGE OF THE TESTING DEVICE TO COUNT THE NUMBER OF COLORED PIXELS CONTAINED ON TEST LINE
912
MOBILE DEVICE APPLICATION CORRELATES LINE INTENSITY WITH ANALYTE CONCENTRATIONS
914
THE MOBILE DEVICE APPLICATION PRESENTS TEST RESULTS BASED ON PIXEL COUNT AND LINE INTENSITY

FIG. 9

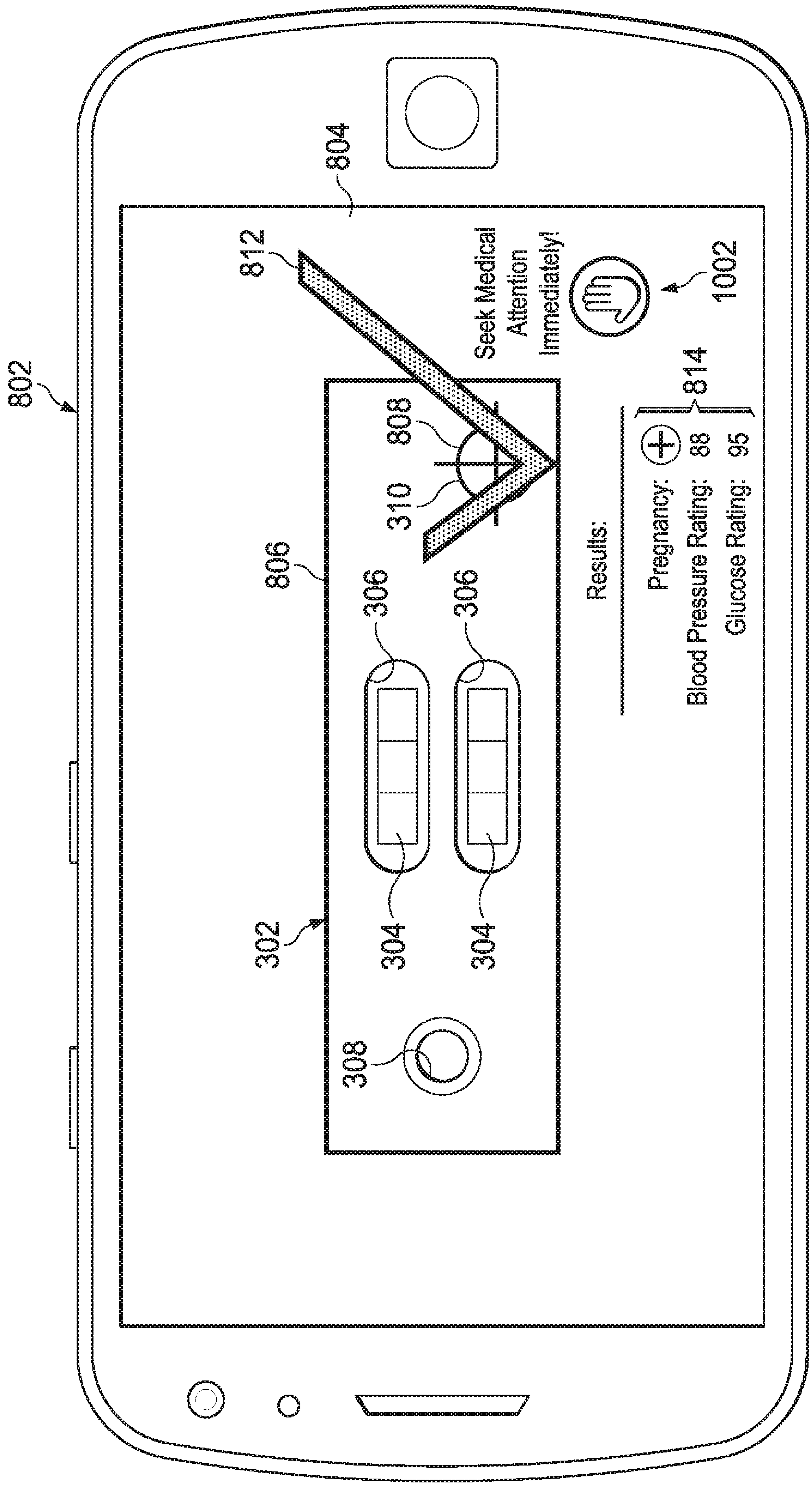
802
804
812
Seek Medical Attention Immediately!
1002
814
806
808
310
306
306
302
304
304
308
Results:
Pregnancy: +
Blood Pressure Rating: 88
Glucose Rating: 95

FIG. 10

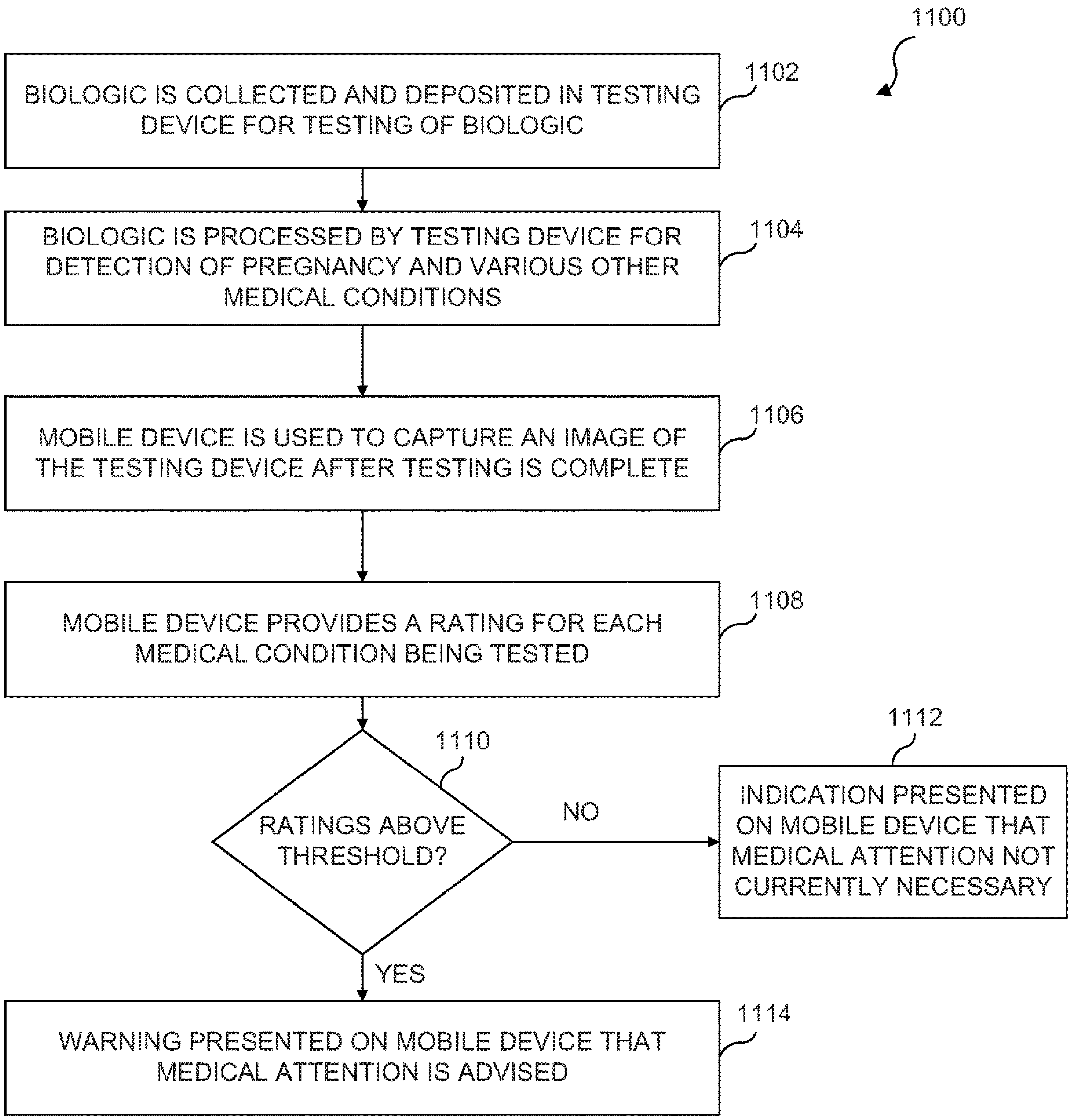
1100
BIOLOGIC IS COLLECTED AND DEPOSITED IN TESTING DEVICE FOR TESTING OF BIOLOGIC
1102
BIOLOGIC IS PROCESSED BY TESTING DEVICE FOR DETECTION OF PREGNANCY AND VARIOUS OTHER MEDICAL CONDITIONS
1104
MOBILE DEVICE IS USED TO CAPTURE AN IMAGE OF THE TESTING DEVICE AFTER TESTING IS COMPLETE
1106
MOBILE DEVICE PROVIDES A RATING FOR EACH MEDICAL CONDITION BEING TESTED
1108
RATINGS ABOVE THRESHOLD?
1110
NO
INDICATION PRESENTED ON MOBILE DEVICE THAT MEDICAL ATTENTION NOT CURRENTLY NECESSARY
1112
YES
WARNING PRESENTED ON MOBILE DEVICE THAT MEDICAL ATTENTION IS ADVISED
1114

FIG. 11

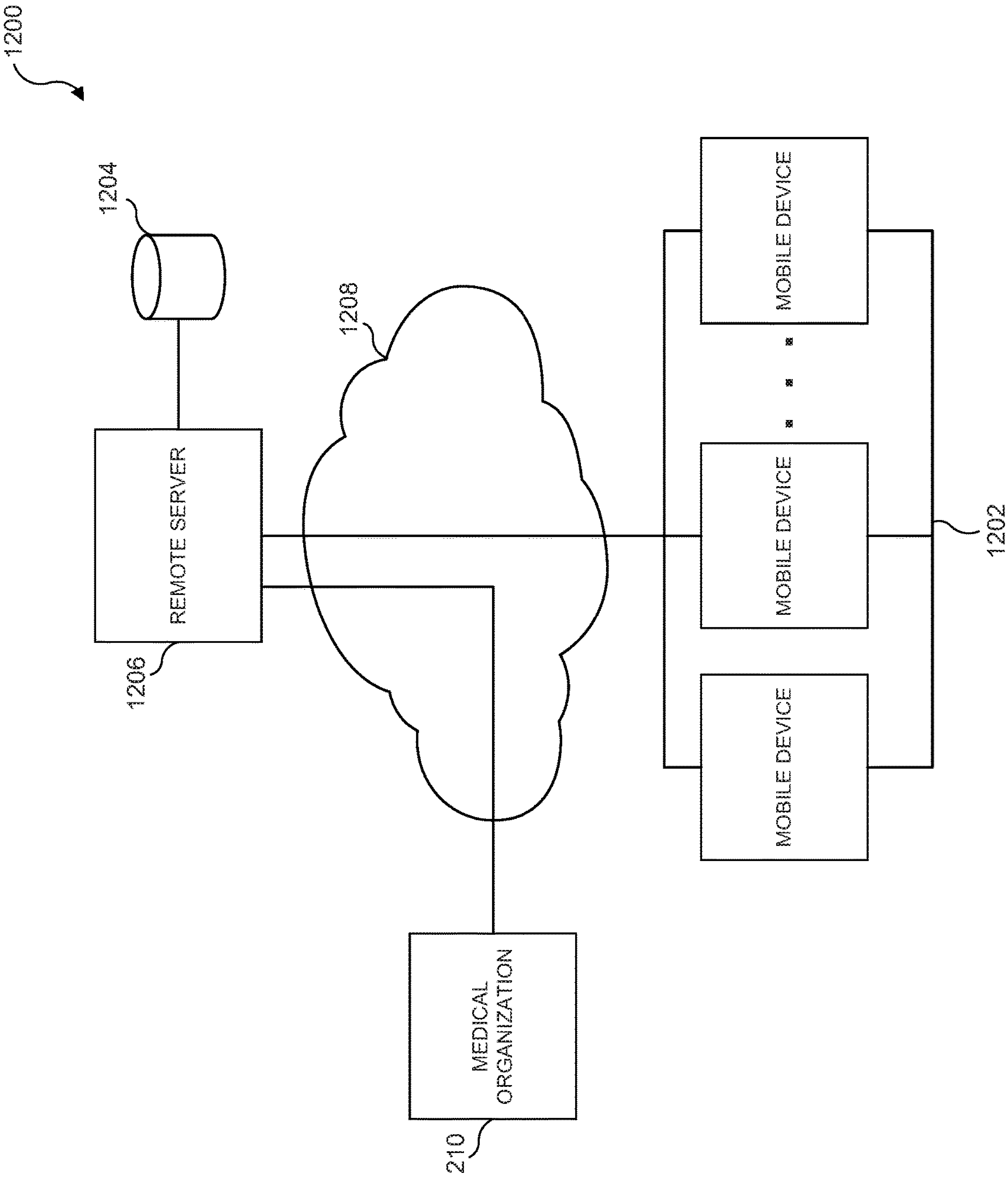
1200
1204
1208
REMOTE SERVER
1206
MOBILE DEVICE
MOBILE DEVICE
MOBILE DEVICE
1202
MEDICAL ORGANIZATION
1210

FIG. 12

1300

1302

1304

BIOLOGIC ID # 2402	
BIOLOGIC TYPE	BLOOD
PREGNANCY RATING	99
ZIKA INFECTION RATING	75
GLUCOSE RATING	10

1304

FIG. 13

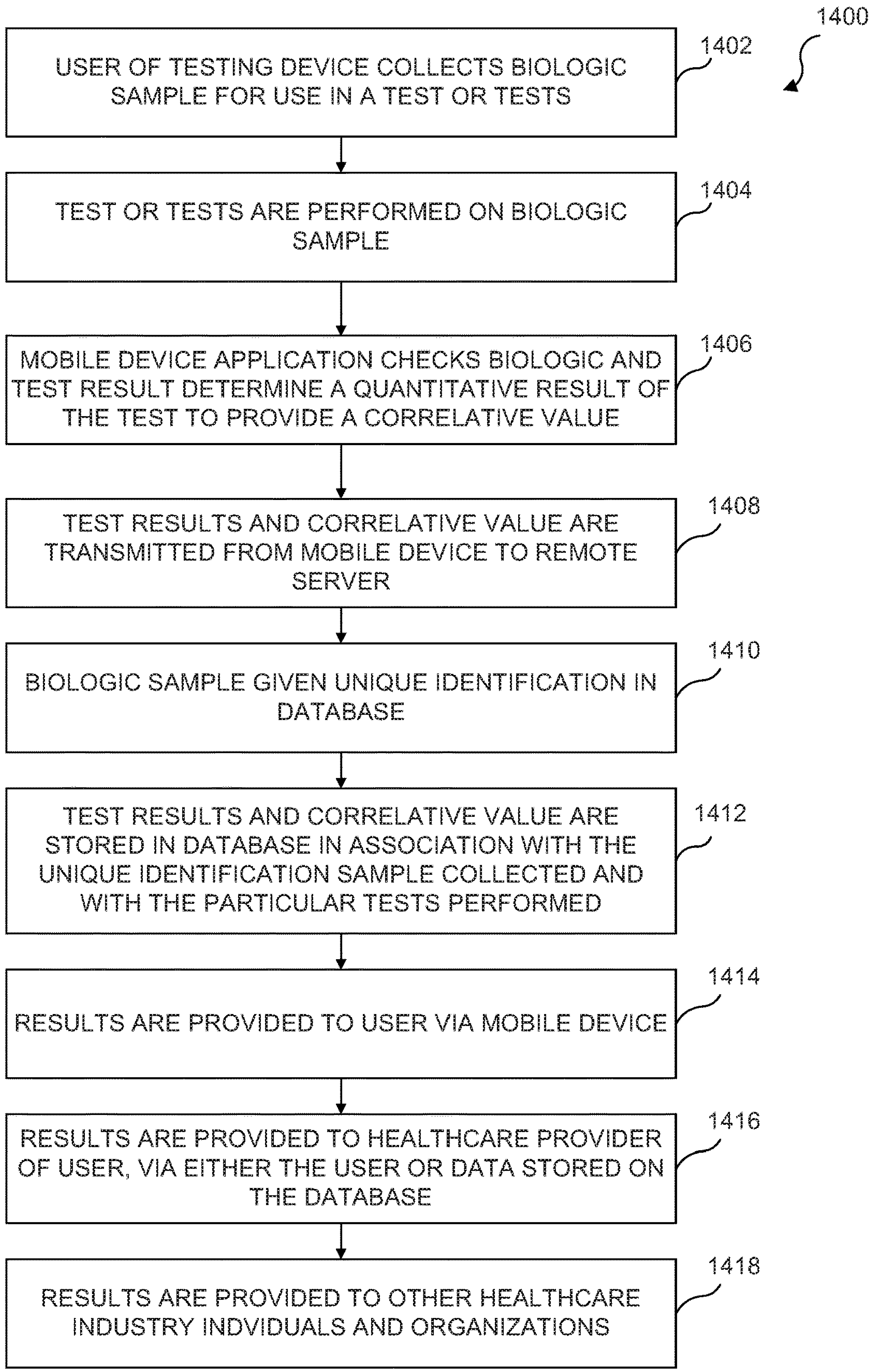
1400
1402
USER OF TESTING DEVICE COLLECTS BIOLOGIC SAMPLE FOR USE IN A TEST OR TESTS
1404
TEST OR TESTS ARE PERFORMED ON BIOLOGIC SAMPLE
1406
MOBILE DEVICE APPLICATION CHECKS BIOLOGIC AND TEST RESULT DETERMINE A QUANTITATIVE RESULT OF THE TEST TO PROVIDE A CORRELATIVE VALUE
1408
TEST RESULTS AND CORRELATIVE VALUE ARE TRANSMITTED FROM MOBILE DEVICE TO REMOTE SERVER
1410
BIOLOGIC SAMPLE GIVEN UNIQUE IDENTIFICATION IN DATABASE
1412
TEST RESULTS AND CORRELATIVE VALUE ARE STORED IN DATABASE IN ASSOCIATION WITH THE UNIQUE IDENTIFICATION SAMPLE COLLECTED AND WITH THE PARTICULAR TESTS PERFORMED
1414
RESULTS ARE PROVIDED TO USER VIA MOBILE DEVICE
1416
RESULTS ARE PROVIDED TO HEALTHCARE PROVIDER OF USER, VIA EITHER THE USER OR DATA STORED ON THE DATABASE
1418
RESULTS ARE PROVIDED TO OTHER HEALTHCARE INDUSTRY INDVIDUALS AND ORGANIZATIONS

FIG. 14

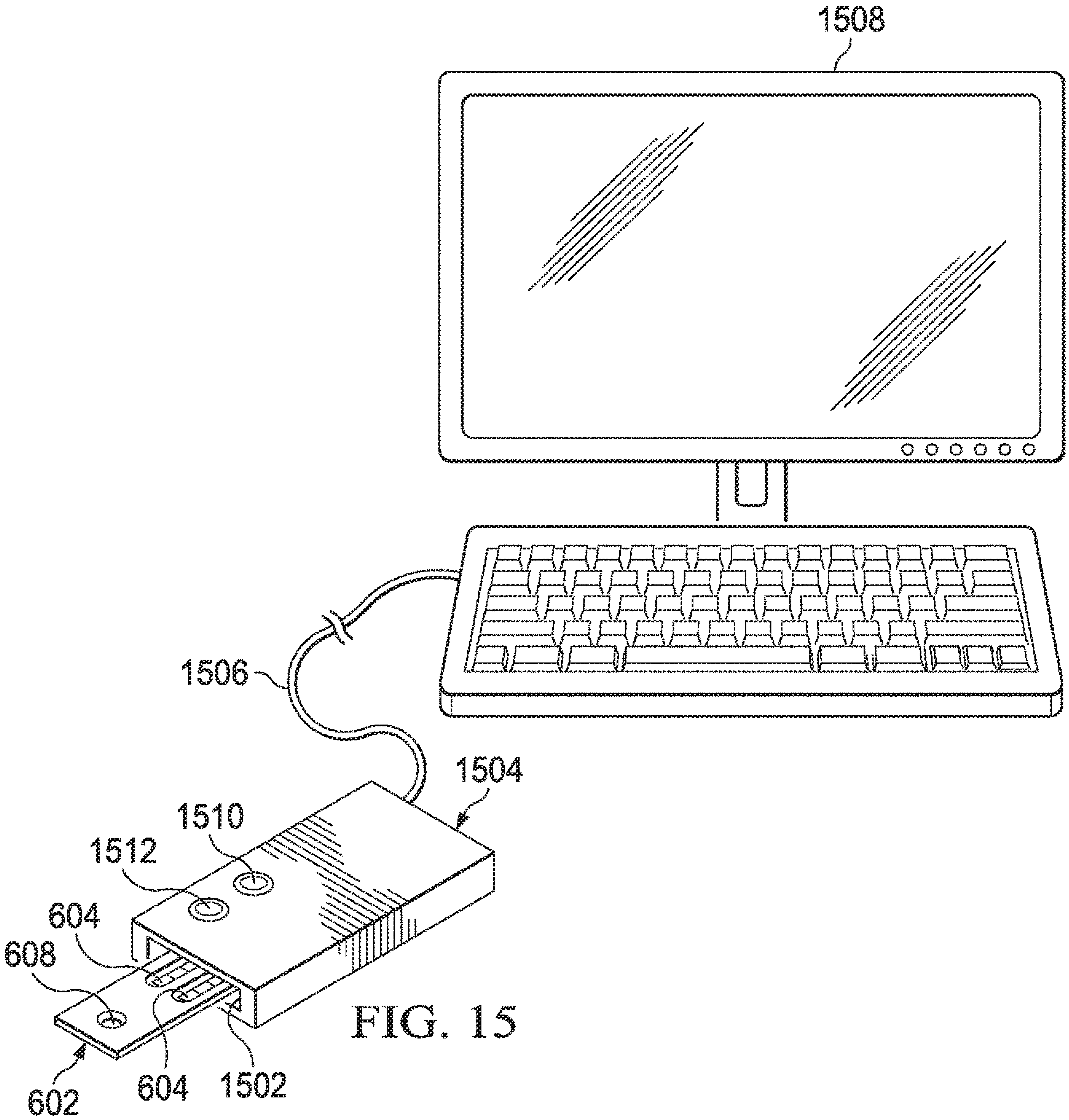
1508
1506
1504
1510
1512
604
608
602
604
1502

FIG. 15

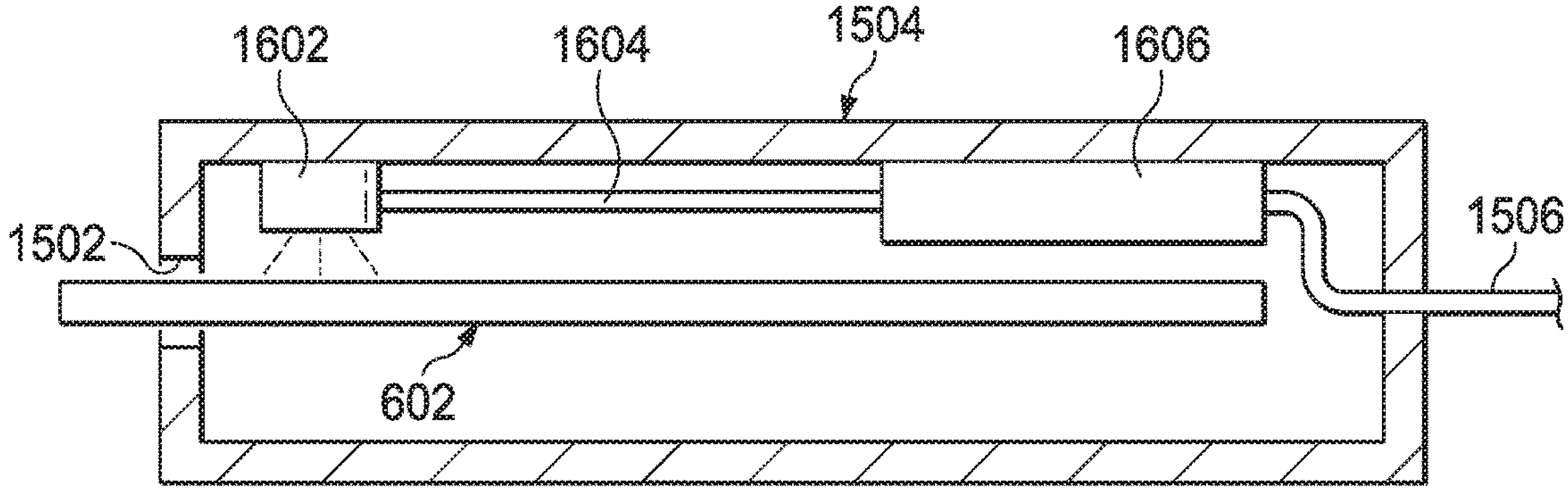
1602
1604
1504
1606
1502
1506
602

FIG. 16

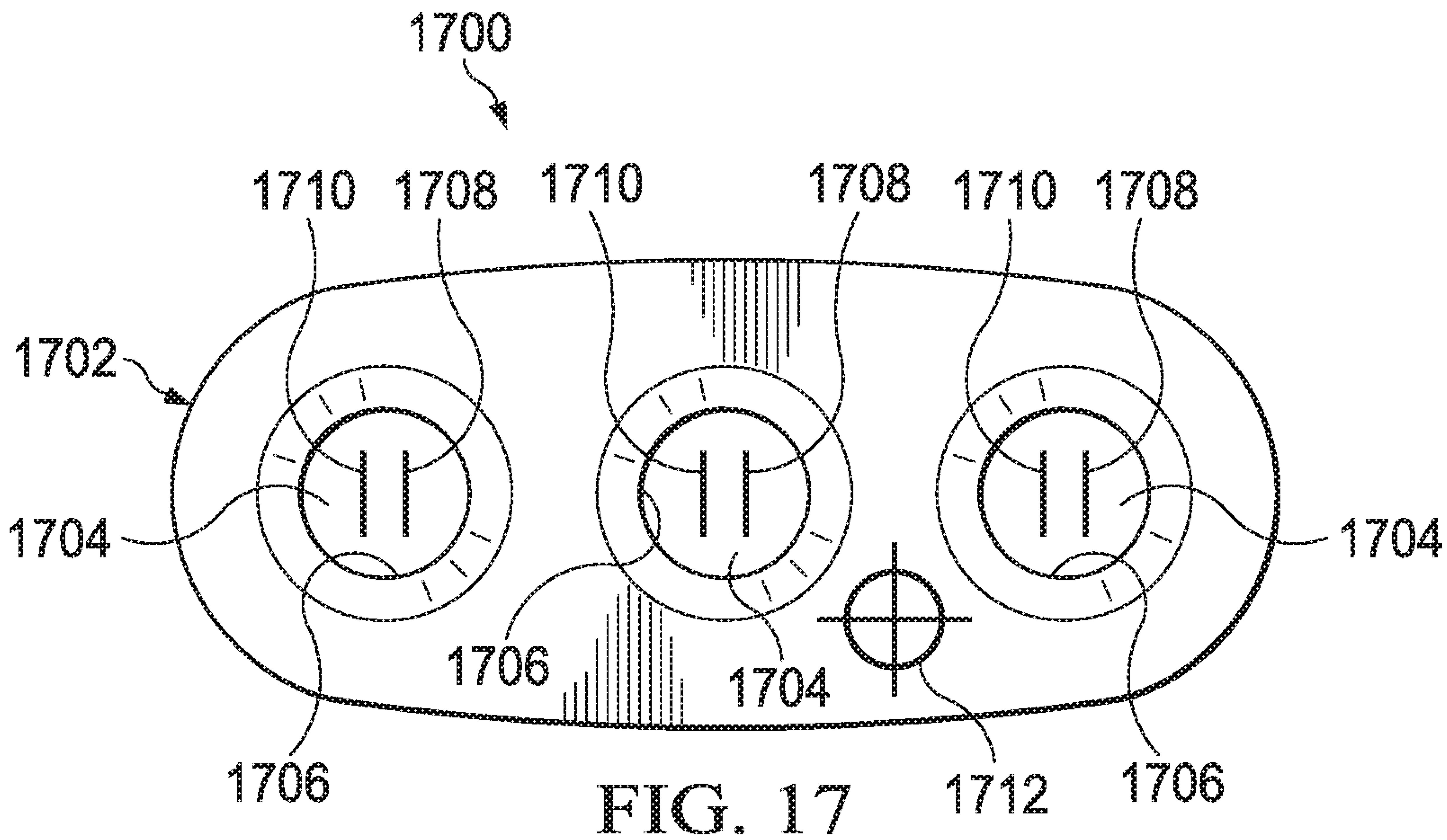
1700
1710
1708
1710
1708
1710
1708
1702
1704
1704
1706
1704
1706
1712
1706

FIG. 17

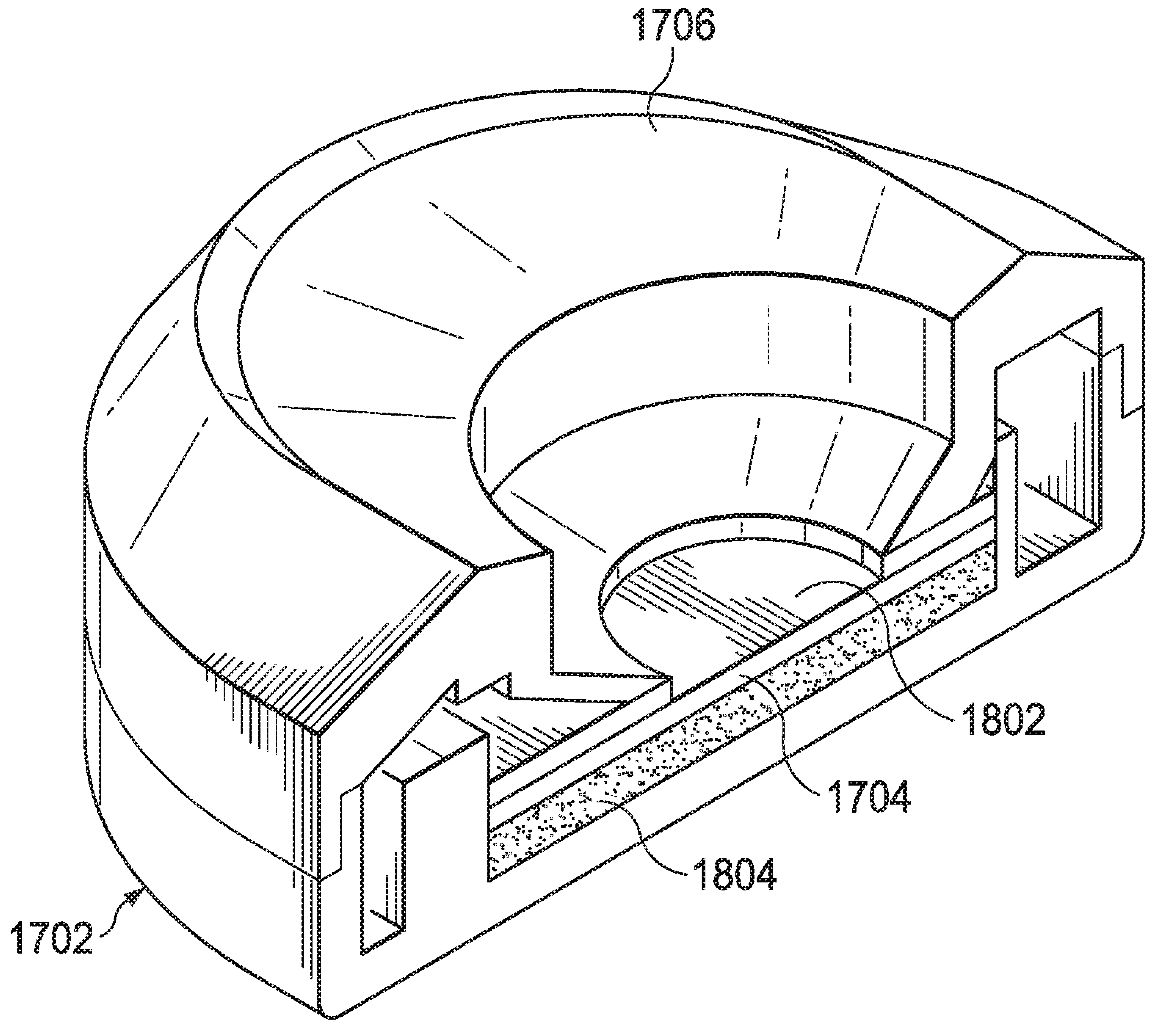
1706
1802
1704
1804
1702

FIG. 18

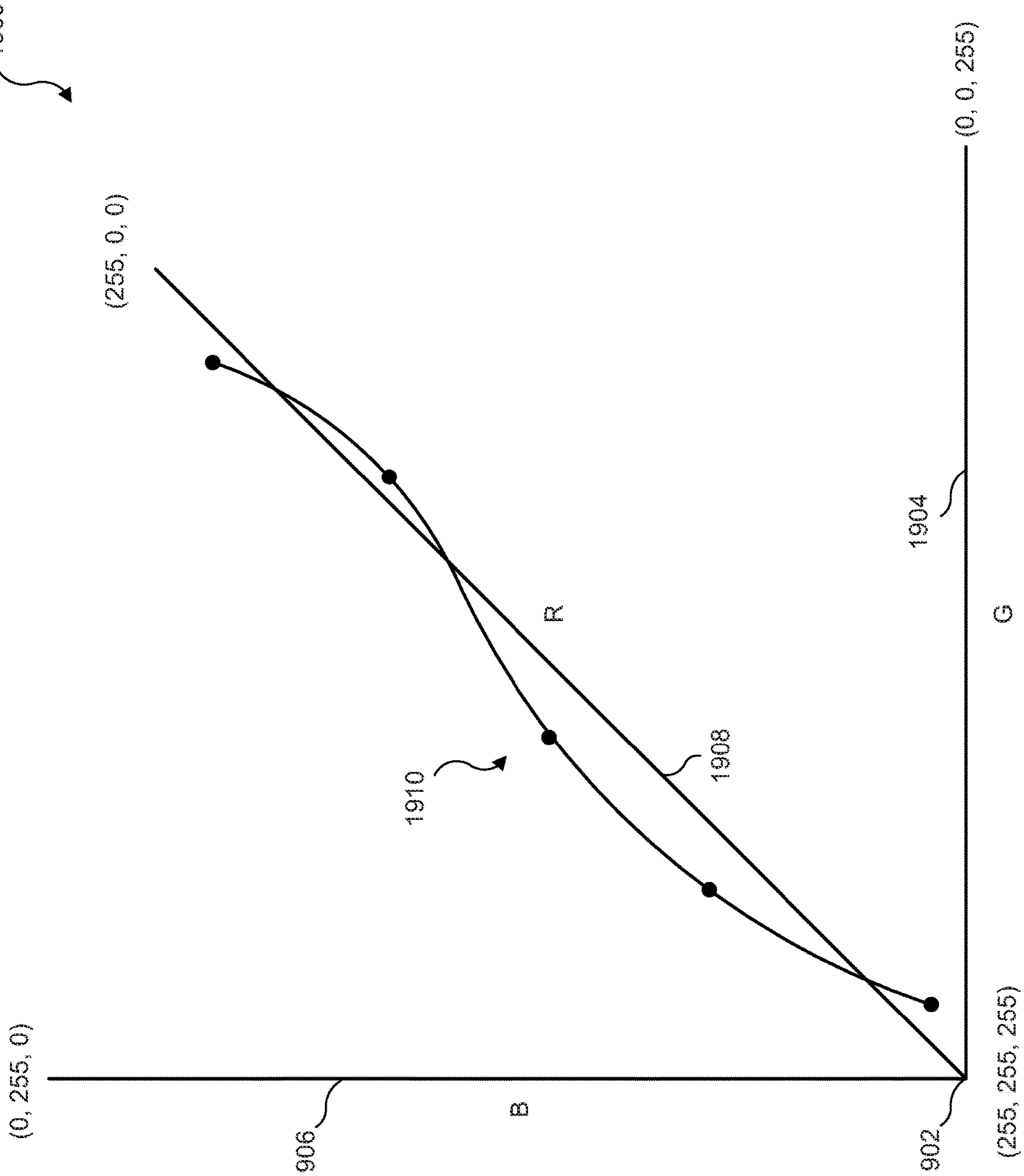
1900
(255, 0, 0)
(0, 0, 255)
1904
R
G
1910
1908
(0, 255, 0)
1906
B
1902
(255, 255, 255)

FIG. 19

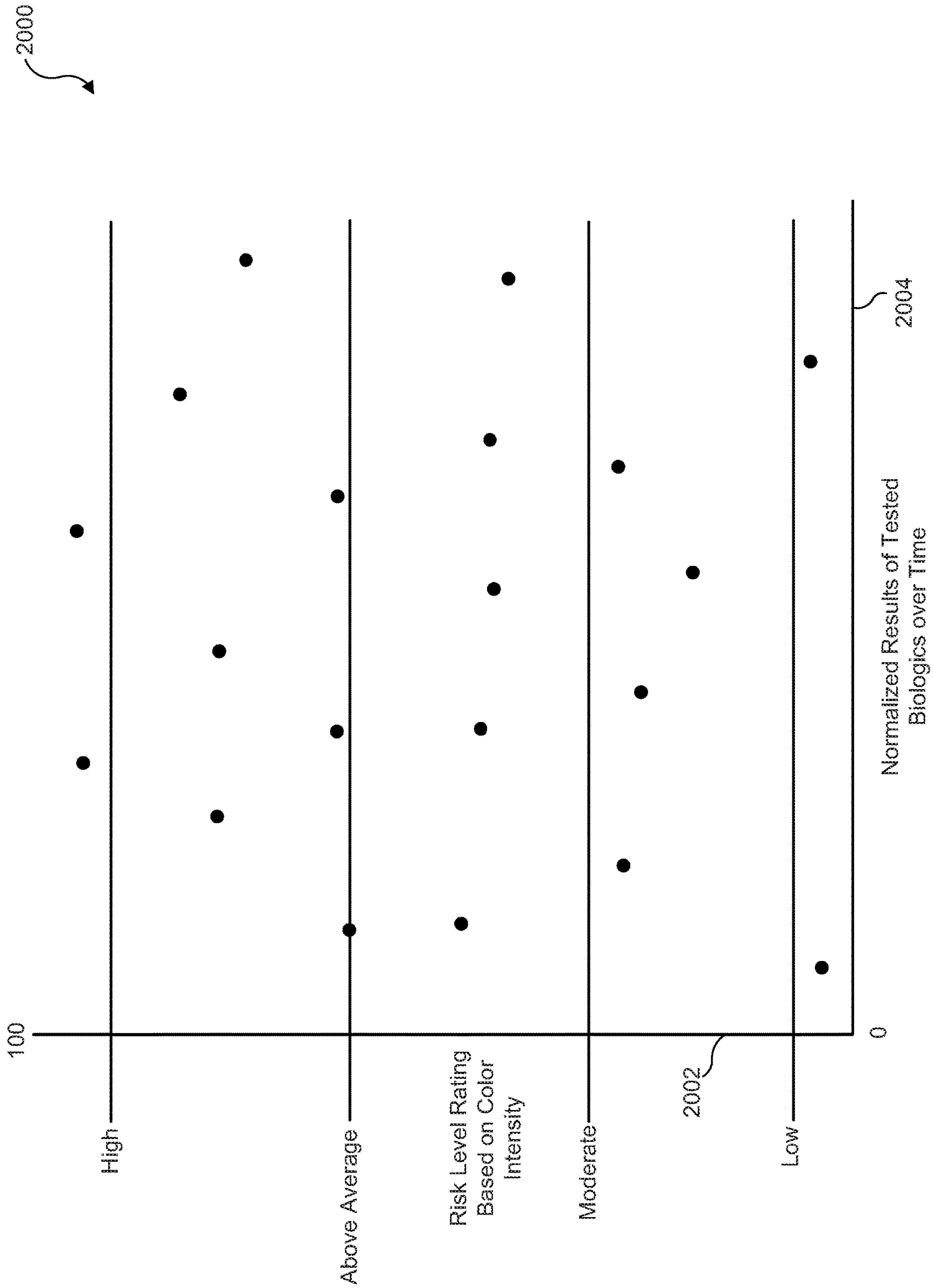
2000
100
High
Above Average
Risk Level Rating Based on Color Intensity
Moderate
2002
Low
0
2004
Normalized Results of Tested Biologics over Time

FIG. 20

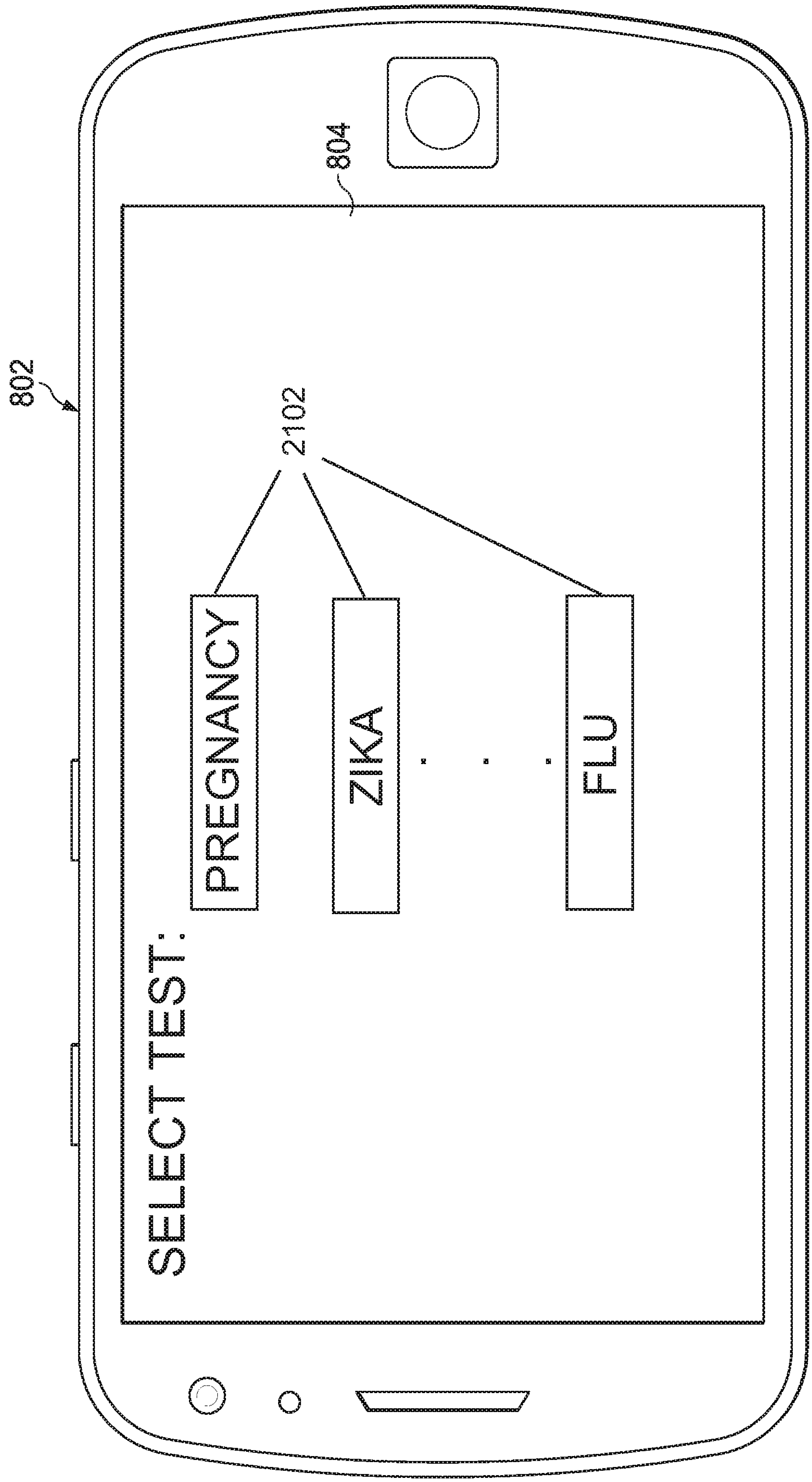

FIG. 21

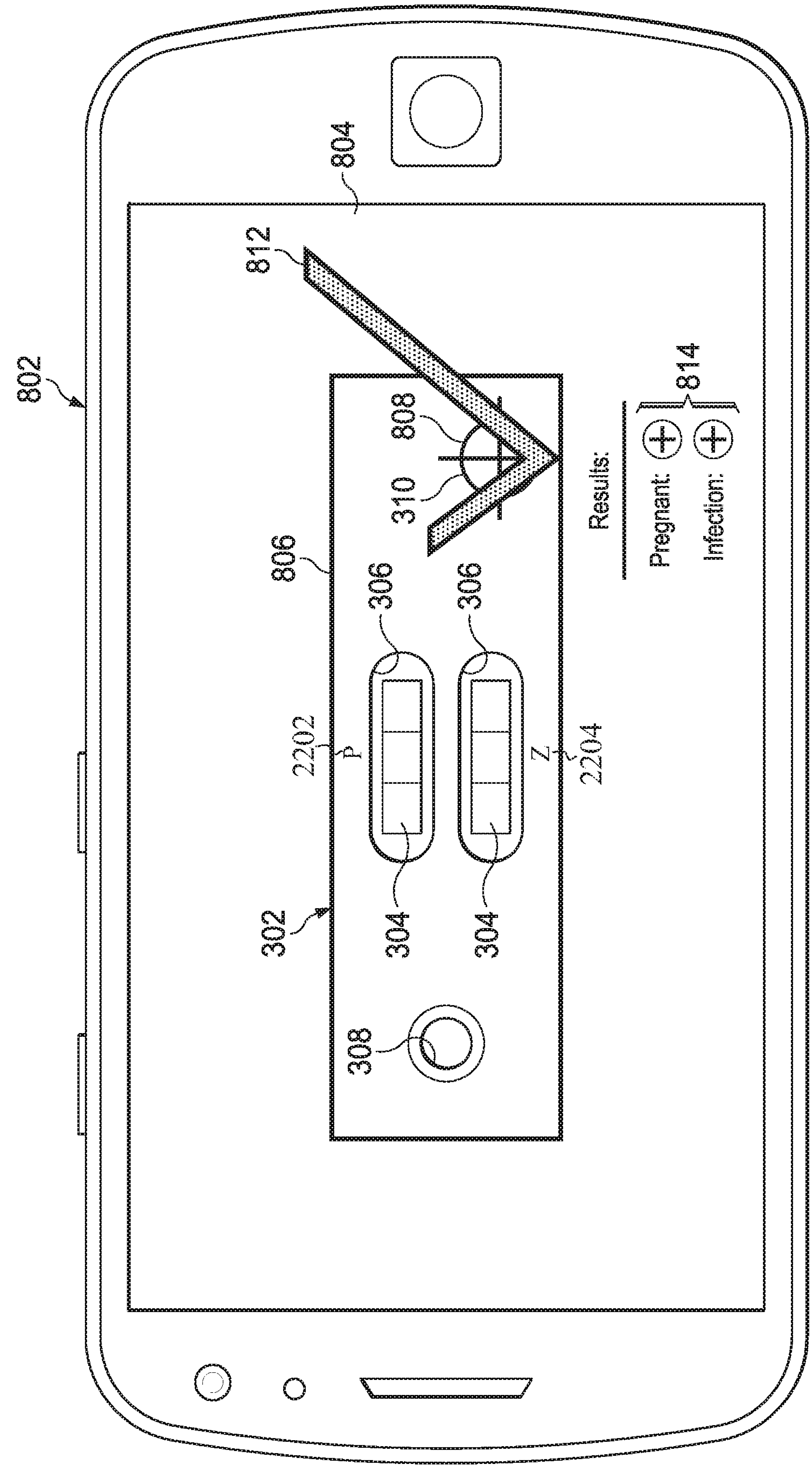
802
804
812
806
808
310
814
Results:
Pregnant:
Infection:
306
306
2202
P
Z
2204
302
304
304
308

FIG. 22

SYSTEM AND METHOD FOR VARIABLE FUNCTION MOBILE APPLICATION FOR PROVIDING MEDICAL TEST RESULTS USING VISUAL INDICIA TO DETERMINE MEDICAL TEST FUNCTION TYPE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 15/295,398, filed on Oct. 17, 2016, and entitled PREGNANCY TEST TO ASSESS DISEASE RISK (Atty. Dkt. No. RIDL-33308). This application also claims benefit of U.S. Provisional Application Ser. No. 62/419,382, filed on Nov. 8, 2016, and entitled SYSTEM AND METHOD FOR VARIABLE FUNCTION MOBILE APPLICATION FOR PROVIDING MEDICAL TEST RESULTS USING VISUAL INDICIA TO DETERMINE MEDICAL TEST FUNCTION TYPE (Atty. Dkt. No. RIDL-33371).

TECHNICAL FIELD

The following disclosure is related to biologic data collection and, more specifically, storage and dissemination of biologic characteristics data.

BACKGROUND

When conducting testing on biologic materials, the biologic material may have various uses beyond the test, and data on such can be valuable at a later time. Therefore, what is needed is a system and method for storage of data on particular biologic samples and for providing access to same.

SUMMARY

In one aspect thereof, a system for providing medical test results is provided. The system comprises a mobile device application configured to provide a plurality of medical test functions, and a server configured to receive information from a mobile device application regarding test results from a test performed using a testing device, wherein the testing device includes a plurality of immunoassay test strips and at least one test function indicator on a surface thereof, wherein the mobile device application is configured to recognize the at least one test function indicator to trigger performance of one or more of the plurality of medical test functions, receive an image of the testing device from the mobile device application, determine RGB values for a plurality of pixels of the image, normalize the RGB values into a single value, compare the single value to a control value stored on the server, and provide a risk indicator, wherein the risk indicator indicates a likelihood of a presence of a medical condition.

In another aspect thereof, a method for image analysis of medical test results is provided. The method comprises receiving, at a server, information from a mobile device application regarding test results from a test performed using a testing device, wherein the testing device includes a plurality of immunoassay test strips and at least one test function indicator on a surface thereof, wherein the mobile device application is configured to recognize the at least one test function indicator to trigger performance of one or more of the plurality of medical test functions, receiving at the server an image of the testing device from the mobile device application, determining by the server RGB values for a plurality of pixels of the image, normalizing by the server the RGB values into a single value, comparing by the server the single value to a control value stored on the server, and providing by the server a risk indicator, wherein the risk indicator indicates a likelihood of a presence of a medical condition.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding, reference is now made to the following description taken in conjunction with the accompanying Drawings in which:

FIG. **1** illustrates a diagrammatic representation of one embodiment of a immunoassay test strip;

FIG. **2** illustrates a diagrammatic representation of one embodiment of an immunoassay test wherein an analyte is tested across a plurality of test strips;

FIG. **3** illustrates a diagrammatic representation of one embodiment of a testing device;

FIG. **4** illustrates a top view of the testing device of FIG. **3**;

FIG. **5** illustrates a top view of one embodiment of a testing device;

FIG. **6** illustrates a top view of another embodiment of a testing device;

FIG. **7** illustrates a flowchart of one embodiment of a testing device use method;

FIG. **8**A illustrates a diagrammatic representation of one embodiment of a process for a mobile device application for testing device image capture and image processing, wherein an image alignment indicator is not aligned with the subject of the image;

FIG. **8**B illustrates a diagrammatic representation of one embodiment of a process for a mobile device application for testing device image capture and image processing, wherein an image alignment indicator is aligned with the subject of the image;

FIG. **9** illustrates a flowchart of one embodiment of an image analysis process using a mobile device;

FIG. **10** illustrates a diagrammatic representation of another embodiment of a process for a mobile device application for testing device image capture and image processing, wherein an image alignment indicator is aligned with the subject of the image;

FIG. **11** illustrates one embodiment of a consumer driven biologic and disease data collection system;

FIG. **12** illustrates one embodiment of a consumer driven biologic and disease data collection system;

FIG. **13** illustrates an example of a unique biologic ID database table;

FIG. **14** illustrates a flowchart of one embodiment of a biologic data collection and dissemination process;

FIG. **15** illustrates a perspective view of a system for scanning test strips;

FIG. **16** illustrates a cross-sectional view of the system of FIG. **15**;

FIG. **17** illustrates one embodiment of a vertical flow immunoassay device;

FIG. **18** illustrates a cross-sectional view of one embodiment of the vertical immunoassay device of FIG. **17**;

FIG. **19** illustrates a color gradient chart;

FIG. **20** illustrates a normalized past tests results rating chart;

FIG. **21** illustrates a mobile device displaying on a screen a mobile application variable test functionality; and

FIG. 22 illustrates the mobile device of FIG. 21, wherein a housing of a testing device also includes thereon test function indicators.

DETAILED DESCRIPTION

Referring now to the drawings, wherein like reference numbers are used herein to designate like elements throughout, the various views and embodiments of an arbovirus indicative birth defect risk test are illustrated and described, and other possible embodiments are described. The figures are not necessarily drawn to scale, and in some instances the drawings have been exaggerated and/or simplified in places for illustrative purposes only. One of ordinary skill in the art will appreciate the many possible applications and variations based on the following examples of possible embodiments.

Referring now to FIG. **1**, there is illustrated one embodiment of an immunoassay test strip **100**. The test strip **100** is typically housed in a testing device configured to collect a biologic analyte **106** from a user and to direct to the biologic analyte **106** onto the testing strip **100**. However, it will be understood that the biologic may be applied onto a strip **100** without the strip **100** needing to be within a testing device. The test strip **100** includes a backing **102**. The test strip **100** is made up of multiple sections disposed on the backing **102**. A sample pad **104** is disposed on one end of the strip **100**, for collecting the biologic analyte **106**. The biologic analyte **106** may be any biologic needed for use in the immunoassay, such as urine, blood, saliva, stool, sweat, or other biologics to be used as an analyte. Various methods may be used to acquire the needed biologic, and such may be provided to the user packaged with the test, such as swabs, vials, containers, dilutants and other solutions, or any other equipment required. In the case of a blood analyte, a few drops of blood may be obtained from a finger stick using a finger prick device. Such a blood analyte may be blood mixed with an adequate amount of buffered solution to create the sample analyte **106** or a blood sample that is not diluted or otherwise manipulated, in which case the blood only is the analyte **106**.

The biologic analyte **106**, after coming into contact with the sample pad **104**, begins to migrate across the strip **100** by capillary action, coming into contact with other sections of the strip **100**. A particle conjugate pad **108** is disposed between the sample pad **104** and a test line **110**. The conjugate pad **108** may contain various reagents associated with a particular antigen, such as a virus, allergen, or bacteria, the reagents being items such antibodies, enzymes, or other reagents needed to diagnose the particular condition. The reagent in the conjugate pad **108** may be conjugated with particles of materials such as colloid gold or colored latex beads. As the analyte **106** migrates through the conjugate pad **108**, antibodies present in the sample analyte **106** complex with the reagents in the conjugate pad **108**, thereby creating an immune complex that will migrate to the test zone or test line **110**.

The test line **110** (T) may be precoated with the relevant antigen in question, i.e., a virus, allergen, or bacteria, for the detection of antibodies associated with the particular antigen. The immune complex created when the analyte **106** passes through the conjugate pad **108** is captured onto the antigen contained on the test line **110**. This may create a qualitative response on the strip where the test line **110** is located, such as a colored response. In some embodiments, the test line **110** may not be a line, but may be other shapes or symbols, such as a plus sign. If no antigen-anti-antigen complexes are present in the analyte, no reaction occurs in the test line **110** and a qualitative response will not occur.

After passing through the test line **110**, the analyte migrates further along the strip to reach a control line **112**, where excess anti-antibody-colloidal gold or latex conjugates get bound. A qualitative response may be shown at the control line **112**, indicating that the sample has adequately migrated across the testing membrane or substrate as intended. It will be understood that the control line **112** is not necessarily needed to perform the test, and may be eliminated entirely, but the control line **112** does provide a comparative example for a user reading the test. For example, the control line **112**, in embodiments where a colored qualitative response is provided, may appear as an overly saturated color, such as a dark or bright saturated red, once the sample reaches the control line **112**. This saturated color may be used as a comparison against the qualitative response shown on the test line **110**. For example, if the qualitative response shown on the test line **110** is a much lighter red than that on the test line **110**, it may be that very little reaction occurred at the test line. Of course, if no response is shown at all at the test line **110**, no reaction has occurred. If the qualitative response at the test line **110** is of a similar saturation to the control line **112**, a strong reaction is indicated.

The strip **100** may not be a continuous substrate. Rather, the various sections of the strip **100** may be separate from each other, but all adhered to the backing **102**. As shown in FIG. **1**, the sample pad **104** and the conjugate pad **108** are separate structures from each other. The test line **100** or zone and the control line **112** or zone are both disposed as part of a nitrocellulose membrane strip**114**. The nitrocellulose membrane strip **114** is also adhered to the backing **102**, but separate from the sample pad **104** and the conjugate pad **106**. As shown in FIG. **1**, the end of the sample pad **104** adjacent to the conjugate pad **106** may overlap the conjugate pad **106**, with that end of the sample pad **106** lying over the adjacent end of the conjugate pad **106**. Similarly, the end of the conjugate pad adjacent to the nitrocellulose membrane strip **114** may lie over the end of the nitrocellulose membrane adjacent to the conjugate pad. This allows for the analyte **106** to be more easily deposited onto each section of the strip **100** as it migrates across the strip **100**. After the analyte **106** migrates across the nitrocellulose membrane strip **114**, and thus across the test line **110** and the control line **112**, the analyte **106** comes into contact with a wick **116** for absorption and collection of the analyte **106**. The end of the wick **116** adjacent to the nitrocellulose membrane strip **114** may lie over that adjacent end of the nitrocellulose membrane strip **114**, as shown in FIG. **1**.

Several Flow Immune Assays have been directed toward identifying proteins, molecules of interest, and even immunoglobulins IgG, IgA, and IgM. IgE is an antibody (immunoglobulin E) that is normally present in the blood freely circulating until it moves into the tissue where it is bound to mast cells through the receptor FcERI (F-C-epsilon-R-one) otherwise known as the high affinity IgE receptor. There is a small amount of IgE bound to IgE receptors (high and low affinity receptors) on basophils, eosinophils, and other cells in the blood and tissues.

Many assay systems are geared toward the detection of infectious proteins. All of the aforementioned tests use a non-human antibody —usually IgG type—e.g., goat IgG antibody directed against a protein of interest to detect the protein of interest from the sample (blood, urine, saliva, sweat, etc.). This antibody complexes with protein of interest and forms a complex that travels across the membrane until it reaches the test zone. In the test zone there is an IgG type antibody directed against IgG from that species of animal. As further described herein, the present detecting apparatus and method use human (patient/consumer-derived) antibodies from the sample and the test zone that contains a humanized antibody directed against the protein of interest that is preconjugated to a detecting substance that results in a visual change.

Summary of Target Antigen:

The target antigens may be proteins, glycoproteins, lipoproteins or other molecular substances capable of eliciting an immune reaction and/or being bound by human specific IgE (sIgE).

Immune assay to detect specific IgE:

In the detecting apparatus and method of using the same, the antigens are proteins conjugated to a noble metal, for example, gold, or latex conjugated to antigen in the test zone, for the purpose of detecting the presence of specific IgE (e.g., anti-peanut IgE in a blood sample from a finger prick). For example, an IgG class antibody (IgGI, IgG2, IgG3, or IgG4) or fragments of those classes of antibodies (fab fragments) whose origin may be any animal species (goat, rat, human, etc.) capable of detecting human IgE (anti-IgE IgG)—a suitable commercially available humanized antibody, such as omaluzimab may be used—may be used to form immune complexes of IgG-anti-IgE-sIgE that will migrate to the test zone having selected specific IgE that can bind to the conjugated antigen.

Immune assay to detect total IgE (not concerned about specific IgE):

Another embodiment includes using an IgG class antibody (IgGI, IgG2, IgG3, or IgG4) or fragments of those classes of antibodies (fab fragments) whose origin may be any animal species (goat, rat, human, etc.) capable of detecting human IgE (anti-IgE IgG)—a suitable commercially available humanized antibody that is preconjugated to a detecting molecule that results in a color change when bound to IgE as the target antigen in the test zone.

Referring now to FIG. **2**, there is illustrated one embodiment of an immunoassay test **200** wherein an analyte **202** is tested across a plurality of test strips **204**. The plurality of test strips **204** may each be configured for testing for a particular antigen. For instance, one strip may be for testing for the presence of streptococcal bacteria (strep throat), one strip may be for testing for a peanut allergy, one strip may be for testing for the Zika virus, etc. Additionally, each strip may also test for multiple antigens. For example, as shown in FIG. **2**, multiple testing panels or lines maybe be incorporated. Each line may be for a particular antigen. As shown in FIG. **2**, multiple test lines **206**, **208**, and **208** may be disposed along the plurality of strips **204**. A strip testing for allergens may have a panel for testing for peanut allergies shown at test line **206** (CHi), for cat allergies shown at test line **208** (CH**2**), or grass allergies shown at test line **210** (CH**3**).

Other examples of configurations for the testing panels can be, but are not limited to: 1) Food **5**: Peanut, milk, soy, wheat, egg; 2) Nut and seed panel: almond, cashew, hazelnut, peanut, pecan, walnut, sesame seed, sunflower seed; 3) seafood: crab, lobster, shrimp, salmon, tuna; 4) Pets: cat, dog; 5) Indoor allergens: dust mites, mold mix (*alternaria, aspergillus, penicillium, cladosporium*), cat, dog; and 6) seasonal allergens: grass (Bermuda, bahia, Johnson, rye, timothy), trees (oak, elm, cedar, mesquite, pine, etc.), weeds (pigweed, ragweed, sage, Russian thistle).

With respect to other non-allergen antigens, the panels may be for testing for strep, Zika, flu, anthrax, cold viruses, cancer, HPV, Lyme disease, mononucleosis (mono), and other illnesses, and/or other conditions such as pregnancy (hCG detection) and disease risks. Some embodiments may allow for the testing of various arboviruses (arthropod-borne viruses). Arboviruses are viruses that are transmitted by arthropods, with mosquitos being a common vector for the virus. Vectors are organisms that transfer the virus from a host that carries the virus. Thus, in the case of mosquitos, a mosquito that feeds on a host that is infected with a virus may infect others when that mosquito again feeds on an uninfected host. Well-known arboviruses include Dengue virus, Japanese encephalitis virus, Rift Valley fever virus, West Nile virus, yellow fever virus, chikungunya, and Zika virus. Urine, blood, and saliva and other biologics may be used for arboviruses testing.

Certain antigens or medical conditions may be logically paired together. For instance, a testing device may include both a strip for detection of pregnancy and a strip for the detection of the zika virus, as the Zika virus has been known to cause birth defects in infants born to pregnant women that are infected with Zika. Thus, combining these two tests into a single testing device or kit would alert a woman to a potential Zika infection proximate in time to the time she also discovers she is pregnant, allowing the woman to seek medical attention immediately. This is a substantial improvement over past Zika testing, where a woman may be required to wait weeks before results are returned from a lab after having the biologic collected by her physician. In many cases, this may lead to a woman having passed a state-mandated cutoff point for abortions, such as 24 weeks in some states. Combining a Zika test with a pregnancy test and physically linking the two tests, and thus allowing for a woman to determine a Zika risk at the time of taking a pregnancy test, in which a pregnancy test may be taken as soon as six days after conception, allows for that woman to take action much sooner than the state mandated cutoff and waiting for lab results would allow.

Various testing devices that include the test strip **100** or strips may be used, such as a slide that supports the test strip **100**, a cassette based diagnostic test, a dipstick, or combinations thereof. The test results in various embodiments may be in the form of a visual qualitative reading test, a visual semiquantitative format, a reader quantitative assay format, and/or combinations thereof. Additionally, an electronic implementation may be used where the result is displayed digitally on a screen disposed within the apparatus, and visible to the user.

The apparatus and method of detection may be a "one-step" approach from sample to reading without sample dilution or other sample manipulation. The sample may be diluted or endure other sample manipulation, for example the blood sample is diluted with a buffer.

Referring now to FIG. **3**, there is illustrated a diagrammatic representation of one embodiment of a testing device **300**. The testing device **300** includes a housing **302** that forms the body of the testing device. The housing **302** may be made of plastic, metal, or any material durable enough for shipping and subsequent handling by a user. The housing **302** may be hollow so that a plurality of test strips **304** may be housed within and so that a biologic may be deposited within the housing **302**. The testing device **300** may further have a plurality of windows **306**, each window being associated with one of the plurality of test strips **304**, and allowing for a user to view at least the section of the nitrocellulose membrane strip **114** where the test line **110** and control line **112** are located. The plurality of windows **306** may be open, or covered with plastic, glass, or other materials that allow for viewing the plurality of strips **304**. A sample well **308** may be disposed on a surface of the housing **302** to allow a user to deposit a biologic into the housing **302**. The sample well **308** would be disposed over or near the sample pad **104** of the test strip or strips **100**. In the embodiment shown in FIG. **3**, a single sample well **308** is included for collection of a single type of biologic for testing, with each of the plurality of strips **304** being suited for testing for antigens using that particular biologic sample type. For example, if the testing device **300** is a combined pregnancy and Zika test, having both a pregnancy strip and a Zika strip, a urine sample may be deposited into the sample well **308**, causing the urine sample to come into contact with the sample pad **104** on both the pregnancy strip and the Zika strip. It will be understood that both of these tests may also be performed with a blood sample.

The testing device **300** may also have disposed on the surface of the housing a crosshair symbol **310**, used as an alignment target. This symbol may be a graphic printed or adhered to the testing device **300**. The crosshair symbol **310** is used to align the testing device **300** for the taking of an image of the testing device **300** using a camera on a mobile device, for use in a mobile device application described herein. In other embodiments, the crosshair symbol **310** may be other types of symbols, such as a simple shape (circle, square, etc.), other images (such as a medical cross symbol, an arrow, etc.), or any other type of image.

Referring now to FIG. **4**, there is illustrated a top view of the testing device **300**. There is again shown the housing **302**, the plurality of test strips **304**, the plurality of windows **306**, the sample well **308**, and the crosshair symbol **310**.

Referring now to FIG. **5**, there is illustrated a top view of one embodiment of a testing device **500**. The testing device **500** includes a housing **502** having a plurality of test strips **504** within the housing **502** and a plurality of windows **506** for display of the plurality of strips **504**. The housing **502** also includes a plurality of sample wells **508** disposed on one side of the testing device **500**. Each of the plurality of sample wells **508** is associated with one of the plurality of test strips **504** and each of the plurality of sample wells **508** may be disposed over one of the sample pads **104** on the associated one of the plurality of test strips **504**. This allows for a biologic to be deposited into each of the plurality of sample wells **508**, with each well **508** serving to transfer the biologic to the test strip underneath the sample well. The testing device **500** further includes a crosshair **510**. The crosshair symbol **510** is used to align the testing device **500** for the taking of an image of the testing device **500** using a camera on a mobile device, for use in a mobile device application described herein.

Referring now to FIG. **6**, there is illustrated a top view of another embodiment of a testing device **600**. The testing device **600** includes a housing **602** having a plurality of test strips **604** within the housing **602** and a plurality of windows **606** for display of the plurality of strips **604**. The housing **602** also includes a plurality of sample wells **608**. In this embodiment, the sample wells are located on different ends of the housing **602**. In the case of a two test strip device, the sample wells **608** are disposed on opposite ends of the testing device **600**. The strips **604** would be arranged within the housing in such a way as to allow the sample pad **104** on each of the strip to be disposed underneath one of the sample wells **608**. This is useful for testing devices that require different biological samples. For example, if the testing device **600** required a urine sample for one strip and a blood sample for the other strip, having the wells **608** disposed on opposite sides of the testing device would reduce the likelihood that a urine sample, for instance, might be inadvertently deposited into the well designated for the blood sample. In embodiments where there are more than two strips, and more than two wells, the well positions may alternate between the two sides of the testing device. For instance, a first well for a first strip might be disposed on the left side of the testing device, a second well for a second strip might be disposed on the right side of the testing device, a third well for a third strip might be disposed on the left side of the testing device, a fourth well for a fourth strip might be disposed on the right side of the testing device, and so on. The testing device **600** further includes a crosshair **610**. The crosshair symbol **610** is used to align the testing device **600** for the taking of an image of the testing device **600** using a camera on a mobile device, for use in a mobile device application described herein.

The diagnostic test can, for example, be produced in a various formats for different users, such as, but not limited to, consumer/in-home use where the test is purchased through retail channels which will allow individuals to get an immediate, cost-effective test result that can lead to specific avoidance and treatment through follow-up with a medical professional.

The diagnostic test can be provided to and used by hospitals and clinics to provide rapid, on-site test results that are required to prescribe certain medications, such as omaluzimab, by their FDA labels.

This diagnostic assay can be modified to detect the presence of specific IgE in pets.

It is also noted that housing **602** is designed such that both strips **604** are disposed in physical proximity thereto and in the same actual housing. In this manner, both sets are linked physically to each other such that they cannot be separated and can be associated with a single individual and the actual test cannot be separated. As such, when a patient applies the specimens to the two areas **608** and the test results are exhibited, there is a high probability that two tests were performed at the same time associated with the same patient. Additionally, and electronic chip (not shown) can be embedded within the housing **602** such that the housing **602** can be registered to a specific patient and associated with the medical records of that patient.

Referring now to FIG. **7**, there is illustrated a flowchart of one embodiment of a testing device use method **700**. The method **700** begins at step **702** where a biologic is collected in a sample well or wells of a testing device. The biologic collected may be a non-diluted or non-manipulated biologic, such as blood, urine, or saliva from the user of the test. Diluted or manipulated biologics may be used instead, as required by the specific test. For example, if a viral test requires the biologic to be added to a solution, the biologic could be added to a solution that has previously been placed in a sterilized vial provided with the testing device. After the required amount of time has passed, the solution containing the biologic could be deposited into the well or wells. At step **704**, the biologic contacts a sample pad disposed on a strip or strips within the testing device. At step **706**, the biologic migrates along the strip or strips to come into contact with a conjugate pad containing antibodies. Antibodies present in the biologic will complex with the antibodies in the conjugate pad to create an immune complex. At step **708**, the biologic migrates into a test zone of the strip or strips, coming into contact with an antigen. The antibodies in the conjugate pad serve to provide a means of detection, such as a colored response, if the immune complex binds with the antigen present in the test zone of the strip. At decision block **710**, binding of the antibodies with the antigen may or may not occur depending on if antibodies associated with the antigen are present in the biologic or not. If a binding between the antibodies and the antigen does not occur the process moves to step **712** where no qualitative response is produced on the test line. If a binding does occur, at step **714** a qualitative response is produced on the test line. Whether a binding occurs or not, and whether a qualitative response is produced or not, the process moves to step **716** where the biologic migrates into a control zone of the strip or strips where excess conjugates get bound and produces a qualitative control zone reaction indicating that the sample has adequately migrated across the testing zone.

It will be understood by one skilled in the art that the antibodies and antigens applied to the testing strip may be altered depending on the type of condition being tested. For example, in the case of testing for medical conditions that do not involve an illness or infection, like preganancy, and thus the sample biologic does not contain antibodies associated with the condition, antibodies that react to markers being tested for may be applied to the testing strip instead of an antigen. For instance, pregnancy test requires testing for the presence of hCG. Since hCG is a hormone and not an antibody produced in response to an infection, the testing strip may have antibodies that will react to the presence of hCG applied to the testing zone or line of the testing strip, as well as to the conjugate pad. Similarly, some tests might require antibodies be applied to the testing strip to detect antigens present in the sample, rather than antibodies.

Referring now to FIGS. **8**A and **8**B, there is illustrated a diagrammatic view of one embodiment of a process **800** for a mobile device application for testing device image capture and image processing. The mobile device application allows for an image of a testing device, such as testing device **300**, to be captured using a camera installed on a mobile device **802** having a screen **804**. While the mobile device **802** displays on the screen **804** the scene captured by the camera, the mobile device application also displays a graphic on the screen **804** in the form of a boxed outline **806**, the size of the outline **806** corresponding to the size of the testing device **300**. Also displayed on the screen of the mobile device **802** within or near the outline is a crosshair graphic **808**. A user of the mobile device **802** attempts to align the outline **806** with the borders of the testing device **300** and also attempts to align the crosshair graphic **808** with the crosshair **310** on the testing device **300**. While alignment has not yet been achieved, a misalignment warning **810** may appear on the screen of the mobile device **802**, indicating to the user that alignment has not yet been achieved. Such is shown in FIG. **8**A.

In FIG. **8**B, there is shown the result of a successful alignment of the outline **806** with the testing device **300** and successful alignment of the crosshair graphic **808** with the crosshair **310** on the testing device **300**. As shown in FIG. **8**B, once aligned, a success indicator **812** may appear, such as a check mark or other positive status symbol, on the aligned image. Successful alignment causes the camera on the mobile device **802** to capture the current image of the testing device **300**. Other checks may occur, including ensuring that the image is focused before the image is saved. This image is then processed to determine a result based on the severity of the reaction occurring on the test strip. The mobile device application performs an analysis of the test line captured in the image, counting the number of colored pixels, as well as determining the intensity of the color. The mobile device may then compare this number and color intensity to that in the control line, providing a mathematical evaluation of the test line. Utilizing unique wavelengths of light for illumination in conjunction with either CMOS or CCD detection technology, a signal rich image is produced of the test lines to detect the colloid gold or latex particles. This provides an advantage because a user simply looking at the two lines may not know what the test line indicates, such as when the colored line does appears on the strip, but it is a faded line, rather than a dark line. Based on this analysis, the mobile device application may provide a results indicator **814**.

The results indicator **814** may be a qualitative result or a quantitative result. For example, and as shown in FIG. **8**B, a qualitative result for the results indicator **814** may indicate, in the case of a testing device for testing pregnancy as well as an infection, a plus sign next to a line reading "pregnant:" and a plus sign next to a line reading "infection:" to indicate that the user is both pregnant and infected with the bacteria or virus being tested, such as the Zika virus. For a quantitative result, the results might provide a numeric rating. For instance, a rating system between 1-100 may be used. If the results provide a low rating to the user, such as a rating of **10**, this indicates a low risk of infection, although medical attention may be sought by the user anyway. For example, if the user is pregnant, and also receives a **10** rating for Zika, this may indicate that Zika was detected in low amounts. However, the user may still seek medical attention or further testing from her doctor because Zika has been known to cause birth defects. If the rating is a high rating, such as **95**, this indicates that an infection has most likely occurred and medical attention should be sought immediately.

This same quantitative rating system may be applied to any test (viral infections, bacterial infections, pregnancy, and other health conditions), as the quantitative test can be performed using the software described herein to accurately test bound antibody concentrations on the test strip. In some embodiments, a combined qualitative and quantitative result may be presented, such as both a rating and a plus or minus sign being presented, or other types of quantitative and qualitative indications. Additionally, various combinations of tests may be provided for in the testing device, such as pregnancy/Zika, preganancy/flu, pregnancy/strep/Zika, etc.

Referring now to FIG. **9**, there is illustrated a flowchart of one embodiment of an image analysis process **900** using a mobile device. At step **902** a mobile device application is launched. At step **904** a camera on the mobile device is activated and a crosshair indicator and a testing device outline appear on the mobile device screen. At step **906** the crosshair indicator presented on the screen of the mobile device is aligned with a crosshair icon on the testing device and the device outline presented on the screen of the mobile device is aligned with the borders of a testing device. At step **908**, an indicator of successful alignment is presented on the screen and an image of the testing device is taken by the mobile device camera. At step **910**, the mobile device application processes the image of the testing device to determine test line strength by counting the number of colored pixels contained in the test line. At step **912**, the mobile device application correlates line intensity with analyte concentrations to further determine test line strength. At step **914**, the mobile device application presents the test results based on pixel count and line intensity, providing either a qualitative or quantitative result.

In some embodiments, the number of pixels indicating bound antibodies on the strip may be measured against that in the control line to compare line intensity between the two lines, with the control line acting as an example of a strong reaction, indicating a strong infection, and determining how close the test line intensity is to the control line. This would lead to a logical quantitative result. For instance, if the test line is determined to have a pixel count and line intensity that is 25% of the pixel count and line intensity of the control line, a rating of **25** may be given. If a qualitative result is to be provided, a rating of **25** may give a qualitative result that is negative, or it could be positive depending on the type of condition being tested and known actual infection results where a rating of **25** occurred for that condition.

In some embodiments, the test line may not be compared with the control line to determine a result. Rather, the mobile device application may have access to a database having data on numerous past tests for the same condition. This data may instead be used as the control. This allows the application on the mobile device to retrieve data on past tests and compare the test line data of the current test to past tests. Overall data for past tests may be provided and compared against, such as providing an average or a curve of past tests, or individual tests rated as having accurate results may be compared against.

In addition to a status result of an infection or other medical condition being provided to the user, other indicators of health may also be tested and results thereon provided. This provides for potential early identification of pregnancy and risk of morbidity, allowing for medical attention to be sought much more quickly. Indicators of health may be detected from biologics, such as urine and blood. Urine, for example, allows for the detection of glucose levels, proteins, bacteria, and infectious markers. In the case of glucose, glucose is usually not found in urine, but, if it is, that is an indicator of extremely high levels of glucose in the body, where the kidneys release excess glucose into urine. This is often a sign of diabetes. Protein in the urine may indicate a malfunctioning of the kidneys, which could be the result of high blood pressure. Similarly, if blood is detected in urine, it could be a sign of a problem with the kidneys or the bladder. Blood, for example, allows for the detection of glucose, inflammation, hormones, genetic defect risks, and metabolic endocrine disorders.

Referring now to FIG. **10**, there is illustrated another embodiment of a successful alignment of the outline **806** with the testing device **300** and successful alignment of the crosshair graphic **808** with the crosshair **310** on the testing device **300**, wherein quantitative results for health risk indicators are provided. In this embodiment, the results indicator **814** provides a qualitative result for pregnancy, and quantitative results for other health risk indicators. In the embodiment shown in FIG. **10**, the health risk indicators being tested are markers for blood pressure and for glucose levels. For blood pressure, this is a test for markers in the blood that can be associated with high blood pressure. These could be test for such things as low levels of vitamin D and the such. Studies have shown that patients suffering from essential hypertension will be under oxidative stress and Malondialdehyde (MDA) is the principal and most studied product of polyunsaturated fatty acid pre-oxidation. This can show an indirect correlation with anti-oxidants, particularly with superoxide dismutases (SODs) ($r=0.573$) and catalase ($r=0.633$) representative anti-oxidant are involved in reducing the stress of a patient's biological system during hypertension. Another marker for hypertension is buildup of uric acid, where in uric acid is a marker for xanthine oxidase-associated oxidants and that the latter could be driving the hypertensive response. Additional markers are cortisol, a hormone. The test strips **604** can test for the different biological markers.

The results indicator **814** provides numeric ratings, in this case, **1-100**, with the blood pressure rating being 88 and the glucose rating being 95. This indicates that both blood pressure and glucose are extremely high. Due to this, an additional alert indicator **1002** is presented to the user on the screen of the mobile device, alerting the user to seek medical attention immediately. This is to ensure that the health of both the pregnant woman and the fetus can be checked as close to the time of pregnancy detection as possible and medical attention received if needed.

Referring now to FIG. **11**, there is provided a flowchart of one embodiment of a pregnancy disease risk assessment process **1100**. The process **1100** begins at step **1102** where a biologic is collected and deposited in a testing device for testing of the biologic. At step **1104**, the biologic is processed by the testing device for detection of pregnancy and various other medical conditions. These medical conditions may be high blood pressure, diabetes, bacterial or viral infections, inflammation, an increase in hormone levels, genetic disease markers, and/or metabolic disorders. At step **1106**, a mobile device is used to capture an image of the testing device after testing is complete. In some embodiments, test results may be immediate. In other embodiments, and depending on the medical conditions being tested, the test may take a certain amount of time to complete. In this case, the user of the test would be alerted to this fact in instructions provided with the testing device. Additionally, a visual indicator on the testing device may alert the user that a test is now complete. At step **1108**, the mobile device provides a rating for each medical condition being tested, such as that described with respect to FIG. **10** herein.

At decision block **1110**, it is determined whether the ratings for each condition exceed a certain threshold for that condition. If not, the process **1100** moves to step **1112**, where an indication is presented to the user via the mobile device screen that medical attention is not currently advised or necessary. If at step **1110** it is determined that at least one of the medical conditions being tested rises above a certain threshold, the process **1100** moves to step **1114** where a warning is presented to the user via the mobile device screen that medical attention is advised. The thresholds for medical conditions may not trigger a warning even if a rating exceeds a threshold, if, in the event of multiple tests being performed, the combined test results do not warrant immediate medical attention. For example, if a user is testing for a cold virus, blood pressure, and glucose, and only the cold virus rating is above the threshold, there may not be a warning provided to the user. Additionally, ratings may be weighted or aggregated based on the medical conditions being tested. For example, if blood pressure, inflammation, and glucose are being tested for, and they all are given only moderate ratings that do not rise above the threshold for any condition individually, an warning to seek medical attention may still be provided due to the combination of conditions taken together.

Referring now to FIG. **12**, there is illustrated one embodiment of a consumer driven biologic and disease data collection system **1200**. Data collected from users performing the tests disclosed herein effectively can provide a wealth of information. As tests are performed data may be passed by a plurality of mobile devices **1202** being used by users performing tests to a database **1204**, the database being at a remote server **1206**, over a network **1208**. The user is sourcing a biologic from user's own body. This is done at home, not in a lab, hospital, or clinic. Each particular test would expect a certain type of biologic to be provided. For instance, for a pregnancy test, a urine sample is provided and tested for pregnancy markers. For a stool test, the stool might be dissolved in a vial with a solution provided with the testing device/kit, and tested for various disease or infectious markers. Data and results from the tests may be stored on the database **1204** at the remote server **1206**. As described herein, this data may be used as a control for testing analysis for users of the plurality of mobile devices **1202**. This data may also be used to provide data sets for biologics to a medical organization **1210**. The medical organization **1210** may be doctor's offices, researchers, hospitals, testing labs, and other individuals or organizations that have an interest in the health and analysis of users taking the test and of their biologic samples. In this way, data can be gathered from a variety of biologics tested for a variety of different medical conditions and characteristics.

Referring now to FIG. **13**, there is illustrated an example of a unique biologic ID database table **1300**. The table **1300** is illustrative of the type of data stored in association with data for a biologic transmitted by the plurality of mobile devices **1202** for storage on the database **1204**. A biologic ID header **1302** is provided that shows that the biologic sample has been given a unique ID. All data concerning the biologic may be stored in association with the unique biologic ID. The table **1300** also includes a biologic type entry **1304**. This designates what type of biologic that the biologic associated with the unique ID is, such as blood, urine, stool, saliva, sweat, or other biologics. The table **1300** also provides a plurality of test ratings **1304**, for various tests performed on the biologic. In the example shown in FIG. **13**, a blood biologic is provided having an assigned ID of **2402**, and having been testing for pregnancy markers, the Zika virus, and for glucose levels. The rating for pregnancy was a **99** rating, the rating for a Zika infection was a **75**, and the rating for glucose levels was a **10**. This would indicate that the test subject has an extremely high likelihood of both a pregnancy and a Zika infection, which would have resulted in a warning to seek medical attention at the conclusion of the tests. Other information may also be stored in the database in relation to the biologic, including other condition ratings, time and date each test was performed, user information such as ethnicity, gender, and age, and status indicators such as whether a test subject visited a physician as a result of the tests. The database **1204** thus provides the test subject with a growing collection of information that may be accessed by the test subject. This allows the test subject to present the test results to her physician for medical attention or additional testing, and allows for others who may access the database, such as disease researchers, to have access to data on various biologic samples and their markers.

Referring now to FIG. **14**, there is illustrated a flowchart of one embodiment of a biologic data collection and dissemination process **1400**. The process **1400** begins at step **1402** where a user of a testing device collects a biologic sample for use in a test or a series of tests. At step **1404**, the test or series of tests are performed on the biologic sample. At step **1406**, a mobile device application checks the biologic sample the testing device result to determine a quantitative result of the test to provide a correlative value for the condition being tested in the biologic sample. At step **1408**, the test results and correlative values, or multiple values if multiple tests on the biologic sample were conducted, are transmitted to the remote server **1206**. At step **1410**, the biologic sample is given a unique identification number in the database **1204**. At step **1412**, the test results and correlative value or values are stored in the database **1204** in association with the unique identification number given to the biologic sample collected and in association with the particular tests performed. This way, the particular biologic sample may have various characteristics stored and retrieved

in association with the biologic sample, and the test results may also be retrieved when data on a particular test is needed on a cross-section of users.

At step **1414**, the results are provided to the user on the user's mobile device. At step **1416**, the results are provided to the user's healthcare provider. The healthcare provider may receive the test results due to a visit from the user, the user bringing the results of the test with her on her mobile device, or the healthcare provider may receive the results from the database **1204** if the healthcare provider has permission to access the database **1204**, or if access is granted in anticipation of the user's appointment with the healthcare provider. At step **1418**, the test results are also provided to other healthcare industry individuals and organizations, including medical researchers, hospitals, and others.

Referring now to FIG. **15**, there is illustrated a perspective view of a system for scanning test strips. The housing **604**, as described hereinabove with respect to FIG. **6**, is illustrated as being disposed within a slot **1502** in a test housing **1504**. The test housing **1504** is connected through a line **1506** to a PC **1508**. When the housing **604** containing the test strips **604** after being subjected to the biologics is inserted within the slot **1502**, the test housing **1504** will scan the test strips **604** and analyze the results with the PC **1508**. The PC **1508** will run some type of algorithm that can analyze the results of both of the test strips **604**. There can be provided to indicators **1510** and **1512** on the surface of the test housing **1504**, one being, for example, a ready LED and one being a green LED. The PC **1508**, after analyzing results, can then provide a warning indicator such as lighting up the green LED for a positive indication of pregnancy and the red LED for indicating that there is some issue. As an example, suppose that the second test strip tested for the Zika virus. If so, a warning would be appropriate to output and activate the red LED. There could be any other type of indicator associated with the second test at **604** that, in a combination with the test results of the first test strip, i.e. for testing for the presence of a pregnancy state, testing for such things as diabetes, etc. Further, although only two test strips **604** are illustrated, there could be multiple test strips testing for many different biological issues that may be present in an individual. In this embodiment, by inserting the housing **602** into the test housing **1504** and allowing the PC **1508** to analyze the results, the indicators associated with the test strips can be analyzed with the assumption that all of the test return results were associated with an individual and in proximate time to each other. That means that the individual patient applied biological specimens, such as urine, blood, etc., to the appropriate test strips and, since these were all contained within the same test strip housing **602**, this provides an indication that they are associated with a single patient. Further, the test performed will typically be a test that will provide a very short-term response. Thus, the specimens can be applied to the test strips **604** in the test strip housing **602** and then inserted within the slot **1502** for testing by the PC **1508**.

Referring now to FIG. **16**, there is illustrated a cross-section of the test housing **1504**. It can be seen that the test strip housing **1602** is passed in slot **1502** past the camera **1602**. The camera **1602** is operable to scan a small cross-section of the test strips **604** on the surface thereof as the test strip housing **602** passes thereby. Of course, there could also be a much larger camera provided for taking an entire image of the test strips **604** after being inserted within the test housing **1504**. The camera **1602** is connected via a wire **1604** two in electronics package **1606** to process the information and send it to the PC **1508**. The electronics package **1606** will also drive the indicators **1510** and **1512**.

Referring now to FIG. **17**, there is illustrated one embodiment of a vertical flow immunoassay device **1700**. It will be understood that testing device **300** and other embodiments herein illustrate a lateral flow immunoassay device. However, other types of immunoassay devices may be used. For example, vertical flow immunoassay devices may be used, a two-sided flow through assay, or even a sandwich ELISA test may be run.

The testing device **1700** includes a housing **1702** that forms the body of the testing device. The housing **1702** may be made of plastic, metal, or any material durable enough for shipping and subsequent handling by a user. The housing **1702** may be hollow so that a plurality of immunoassay test pads **1704** may be housed within and so that a biologic may be deposited within the housing **1702**. The testing device **1700** may further have a plurality of sample wells **1706**, each sample well having one of the plurality of immunoassay test pads **1704** disposed within, and allowing for a user to view at least a section of a nitrocellulose membrane of each of the immunoassay test pads **1704**, the membrane **1708** having a test line **1708** and control line **1710**. The testing device **1700** may also have disposed on the surface of the housing a crosshair symbol **1712**, used as an alignment target. This symbol may be a graphic printed or adhered to the testing device **1700**. The crosshair symbol **1712** is used to align the testing device **1700** for the taking of an image of the testing device **1700** using a camera on a mobile device, for use in a mobile device application described herein. In other embodiments, the crosshair symbol **1712** may be other types of symbols, such as a simple shape (circle, square, etc.), other images (such as a medical cross symbol, an arrow, etc.), or any other type of image. In other embodiments, the device **1700** may be configured in such a way as to allow a biologic sample to be deposited into a sample well, and to present the results of the test on the opposite side of the housing. Such a configuration would allow the biologic to flow through the testing pad within the housing, with the reaction occurring on a reactive membrane on the side of the device opposite the sample well, with the device having a window for viewing the results.

Referring now to FIG. **18**, there is illustrated a cross-sectional view of one embodiment of the vertical immunoassay device **1700**. There is shown one of the plurality of immunoassay test pads **1704** residing within the housing **1702** below one of the plurality of sample wells **1706**. The one of the plurality of immunoassay test pads **1704** includes a immunoreactive membrane **1802**, such as the nitrocellulose membranes disclosed herein. The immunoreactive membrane **1802** may have particle conjugates disposed thereon that binds when a biologic sample is received onto the immunoreactive membrane **1802** via the sample well **1706**, if the biologic sample contains the antigens or antibodies, or other indicators, for which the test is configured. The one of the plurality of immunoassay test pads **1704** also includes an absorbent pad **1804** for collection of excess biologic sample. It will be understood that the cross-sectional view illustrated in FIG. **18** shows one well of the plurality of sample wells **1704**. The other wells included in the device **1700** would be configured in a similar manner as that shown in FIG. **18**. There may also be included in the device **1700** an inner separating wall between each of the plurality of immunoassay test pads **1704**, to ensure that excess biologic material that is not adequately absorbed by the absorbent pad **1804** does not contaminate neighboring immunoassay test pads.

Referring now to FIG. **19**, there is illustrated a color gradient chart **1900**. When the mobile application described herein captures an image of the testing device, in some embodiments each pixel that makes up the test line captured in the image is processed to place it on a color gradient scale. In some embodiments, this placement may be done by examining the RGB values of the pixel. For any given test, there may be a visual color indicator (such as a test line) presented to the user of the test to indicate whether a reaction occurred. The color that is to be presented is known for the given test. Additionally, in some embodiments, the strength of the reaction will affect the strength of the color indicator. For example, if a test is supposed to produce a brown colored indicator, an image can be taken of the colored indicator to examine each pixel of the colored indicator to determine the strength of the color produced on the testing device, which indicates the strength of the reaction, and thus the risk level for the user.

The embodiment illustrated in FIG. **19** uses as an example a set of pixel RGB results for a test that produces a red colored indicator on the test strip when a reaction has occurred. There can be seen an origin point **1902** on the chart **1900**, wherein the RGB value is (255, 255, 255) or white. This may represent a no reaction state for the test strip, since the test line on the strip may only appear as a white blank space if no reaction has occurred. An x axis **1904** represents the color green, wherein the amount of green in the pixel decreases as it moves away from the origin in relation to the x axis **1904**. A y axis **1906** represents the color blue, wherein the amount of blue in the pixel decreases as it moves away from the origin in relation to the y axis **1906**. A diagonal line **1908** running in between the x axis **1904** and the y axis **1906** represents the color red, wherein the diagonal line **1908** running through the center of the chart **1900** is a maximum red color all along the diagonal line **1908**. If a pixel has less red than a 255 value, the pixel would be plotted away from the diagonal line **1908** in relation to whichever color is more predominant. For instance, if the pixel has RGB values of (127, 50, 205), a shade of purple, the pixel would be plotted somewhere in the lower right quadrant of the chart **1900**. FIG. **19** further illustrates an example plurality of pixel plot points **1910**, connected by a curved line, wherein the example plurality of pixel plot points **1910** shows tests results that likely indicate a positive reaction, as the plot points are all located near the diagonal line **1908**, demonstrating that the colored indicator was a heavy red color for the most part.

Referring now to FIG. **20**, there is illustrated a normalized past tests results chart **2000**. The captured pixels may be normalized into a single value for determining whether there is a likelihood of infection, pregnancy, or whatever else the test is designed to detect. This may be done in various ways. For example, the shade of red in all the pixels may be averaged to reach a single RGB value. Outliers may be left out so that the average is not heavily skewed, especially when there are few outliers present. This RGB value may then be given a value, such as a risk rating, ranging from 0 to 100. For example, an RGB value of (255, 255, 255) would be given a rating of **0**. An RGB value of (255, 0,0) would be given a rating of **100**. An RGB value of (205, 150, 75) may be given a rating of **70**, and so on. This normalized value may then be used to compare the user of the test to users of past tests to determine a risk level. In some embodiments, the control line and the test line may be captured and the results compared, as well. In addition, the real results of risk levels may also be used to adjust the stored normalized value. For instance, if a particular RGB value that seems to indicate a strong reaction repeatedly was found to not indicate an infection, this value may be adjusted to provide a lower risk rating. For instance, if a physician who saw a patient who had a (**205**, **150**, **75**) RGB value later reported to the operator of the server **1206** that further testing showed no infection was present, and if this trend continued substantially as reported by other physicians or medical organizations, subsequent test results by other test users that were near the RGB value of (205, 150, 75) may be given a lower rating.

Chart **2000** illustrates how past tests results may be collected and used to determine the risk of a current test user. A y axis **2002** represents a risk level rating, ranging from 0 at the origin to **100**. An x axis **2004** represents time, wherein a plurality of normalized test results is plotted on the chart **2000**. The chart **2000** is further divided into sections across the y axis **2002**, indicating various risk level thresholds. For instance, and as illustrated in the chart **2000**, there may be at certain rating levels different thresholds of risk labeled as low, moderate, above average, and high risk levels. These thresholds may be moved over time as more data is accumulated via users conducting tests and the mobile application storing the data on the tests. When a user conducts a test, the user's normalized rating can be plotted similarly to past test results and weighed against them in order to provide a risk level for the user.

Referring now to FIG. **21**, there is illustrated the mobile device **802** displaying on the screen **804** a mobile application variable test functionality. There is displayed on the screen **804** a plurality of test functions **2102**. The plurality of test functions **2102** may be buttons that can be selected by a user to switch between tests within the mobile application. This allows for all test functions to be within the same mobile application. For each test run by the mobile application, data for the particular test chosen is utilized in performing the test, pulling the data from the remote server **1206**.

Referring now to FIG. **22**, there is illustrated the mobile device **802** of FIG. **8**B, wherein the housing **302** of the testing device **300** also includes thereon test function indicators **2202** and **2204**. The test function indicators **2202** and **2204** are visual markers located on the housing **302** that identify to the mobile application the types of tests for which the testing device **300** is configured. These indicators may be any symbol, alphanumeric character, shape, etc. that can be added to the surface of the testing device **300**. The mobile application is programmed to recognize the indicator and perform the test function associated with the indicator. For example, the embodiment illustrated in FIG. **22** shows a "P" symbol for test function indicator **2202** and a "Z" symbol for test function indicator **2204**. In this embodiment, test function indicator **2202** indicates that one test strip in the testing device **300** is a pregnancy test, while test function indicator **2204** indicates that one test strip in the testing device **300** is a Zika test. This is used for merely illustrative purposes, and any recognizable symbol may be used for these two test functions, and any other type of test may have a symbol assigned in this way as well. Further, in some embodiments there may only be one indicator on the housing **302**, even if there are multiple tests. This single indicator would be for the combined test. For example, if the testing device **300** of FIG. **22** had a single symbol of "PZ," this would indicate that the testing device **300** is a combined pregnancy and Zika testing device, allowing for the mobile application to recognize such and perform each test with knowledge of which strip is associated with which test based on the stored data on the testing device associated with the "PZ" symbol.

It should be understood that the drawings and detailed description herein are to be regarded in an illustrative rather than a restrictive manner, and are not intended to be limiting to the particular forms and examples disclosed. On the contrary, included are any further modifications, changes, rearrangements, substitutions, alternatives, design choices, and embodiments apparent to those of ordinary skill in the art, without departing from the spirit and scope hereof, as defined by the following claims. Thus, it is intended that the following claims be interpreted to embrace all such further modifications, changes, rearrangements, substitutions, alternatives, design choices, and embodiments.

What is claimed is:

1. A method for image analysis of medical test results, comprising:

receiving an RGB image of a testing device, the RGB image including a first indicator associated with a first medical test function and a second indicator associated with a second medical test function different from the first medical test function on a surface of the testing device for performing a selection of the first medical test function and the second medical test function responsive to the first indicator and the second indicator respectively, the RGB image including a plurality of pixels each having an RGB value associated therewith;

selecting the first medical test function and the second medical test function for performance responsive to the first indicator and the second indicator in the RGB image;

identifying RGB color values for the plurality of pixels of the RGB image, wherein a portion of the plurality of pixels represents a test line of the testing device;

determining certain ones of the plurality of pixels of the RGB image to have RGB color values that define the certain ones of the plurality of pixels as outliers, based on the identification of the RGB color values;

discarding the certain ones of the plurality of pixels determined to be outliers from remaining pixels of the plurality of pixels;

creating a normalized RGB value from the RGB color values of the remaining pixels, wherein the normalized RGB value is created relative to a selected color of red, green and blue color values of the RGB color values and based upon each of the RGB color values of the remaining pixels, wherein the selected color is associated with the test line of the testing device;

comparing the normalized RGB value to a normalized control RGB value based on the selected first medical test function and the second medical test function; and

providing a condition indicator for each of the first medical test function and the second medical test function, wherein the condition indicator indicates a likelihood of a presence of a medical condition associated with each of the first medical test function and the second medical test function responsive to comparison of the normalized RGB value with the normalized control RGB value based on the selected first medical test function and the second medical test function.

2. The method of claim **1**, wherein the testing device includes:

a sample pad capable of receiving a biologic sample;

a conjugate pad containing particles for conjugating with antibodies or antigens present in the biologic sample; and

a membrane strip having the test line and a control line, wherein the test line and the control line are viewable.

3. The method of claim 1, further comprising:

providing, from a remote server to a mobile device application, data pertaining to each of the first medical test function and the second medical test function, wherein the data for each of the first medical test function and the second medical test function is utilized by the mobile device application in performing one of first medical test function and the second medical test functions.

4. The method of claim 1, wherein the normalized control RGB value is a normalized value of a dataset from previously conducted tests stored on a database.

5. The method of claim 1, wherein the medical test results include a qualitative result.

6. The method of claim 1, wherein the medical test results include a quantitative result.

7. The method of claim 6, wherein the quantitative result is a reaction rating.

8. The method of claim 1, wherein a test line of the test device includes an antibody suitable for binding with hCG.

9. The method of claim 1, wherein a test line of the test device includes Zika virus antigen.

10. The method of claim 1, wherein a test line of the test device includes Zika virus antigen and a second test line of another test device includes an antibody suitable for binding with hCG.

11. A method for image analysis of medical test results, comprising:

receiving an RGB image of a testing device for performing, the RGB image including a single indicator associated with each of a first medical test function and a second medical test function different from the first medical test function on a surface of the testing device for performing a selection of the first medical test function and the second medical test function responsive to the single indicator, the RGB image including a plurality of pixels each having an RGB value associated therewith;

selecting the first medical test function and the second medical test function for performance responsive to the single indicator in the RGB image;

identifying RGB color values for the plurality of pixels of the RGB image, wherein a portion of the plurality of pixels represents a test line of the testing device;

determining certain ones of the plurality of pixels of the RGB image to have RGB color values that define the certain ones of the plurality of pixels as outliers, based on the identification of the RGB color values;

discarding the certain ones of the plurality of pixels determined to be outliers from remaining pixels of the plurality of pixels;

creating a normalized RGB value between 0 and 100 from the RGB color values of the remaining pixels responsive to relative values of each of red color values, green color values and blue color values, wherein the normalized RGB value is created relative to a selected color of the red, green and blue color values of the RGB color values and based upon each of the RGB color values of the remaining pixels, wherein the selected color is associated with the test line of the testing device and indicates a strength of reaction to a medical condition;

comparing the normalized RGB value to a normalized control RGB value based on the selected first medical test function and the second medical test function; and

providing a condition indicator for each of the first medical test function and the second medical test function, wherein the condition indicator indicates a likelihood of a presence of the medical condition associated with each of the first medical test function and the second medical test function responsive to comparison of the normalized RGB value with the normalized control RGB value based on the selected first medical test function and the second medical test function.

12. The method of claim 11, wherein normalized control RGB value comprise past test results from other users.

13. The method of claim 1, wherein the step of creating the normalized RGB value further comprises creating the normalized RGB value between 0 and 100 from the RGB color values of the remaining pixels responsive to relative values of each of the red color values, the green color values and the blue color values.

14. The method of claim 1, wherein the step of comparing further comprises:

comparing the normalized RGB value to a first normalized control RGB value based on the selected first medical test function; and

comparing the normalized RGB value to a second normalized control RGB value based on the selected second medical test function.

15. The method of claim 14, wherein the step of providing further comprises:

providing a first condition indicator, wherein the first condition indicator indicates a likelihood of a presence of a first medical condition responsive to the comparison of the normalized RGB value with the first control normalized RGB value; and

providing a second condition indicator, wherein the second condition indicator indicates a likelihood of a presence of a second medical condition responsive to the comparison of the normalized RGB value with the second control normalized RGB value.

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